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

FORM 10-K

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

For the Fiscal Year Ended September 30, 2019
or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Transition Period from_____ to _____.

Commission File Number 333-88480

NEUBASE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**46-5622433**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

700 Technology Drive, Third Floor, Pittsburgh, PA 15219
(Address of principal executive offices and zip code)

(646) 450-1790
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	NBSE	The Nasdaq Stock Market LLC

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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, 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 any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of January 7, 2020, 17,077,873 shares of the common stock, par value $0.0001, of the registrant were outstanding.

The aggregate market value of the voting stock held by non-affiliates of the registrant the last business day of the registrant's most recently completed second fiscal quarter: $5.8 million based upon the closing sale price of our common stock of $2.25 on that date. Common stock held by each officer and director and by each person known to own in excess of 10% of outstanding shares of our common stock has been excluded in that such persons may be deemed to be affiliates. The determination of affiliate status in not necessarily a conclusive determination for other purposes.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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As previously disclosed on July 12, 2019, Ohr Pharmaceutical, Inc., a Delaware corporation ("Ohr"), completed a Merger with NeuBase Therapeutics, Inc., a Delaware corporation ("Legacy NeuBase"), in accordance with the terms of the Agreement and Plan of Merger Reorganization (the "Merger Agreement") entered into on January 2, 2019. Pursuant to the Merger Agreement, (i) a subsidiary of Ohr merged with and into Legacy NeuBase, with Legacy NeuBase (renamed as "NeuBase Corporation") continuing as a wholly-owned subsidiary of Ohr and the surviving corporation of the merger and (ii) Ohr was renamed as "NeuBase Therapeutics, Inc." (the "Merger").

For accounting purposes, the Merger is treated as a "reverse asset acquisition" under generally accepted accounting principles in the United States ("U.S. GAAP") and Legacy NeuBase is considered the acquirer. Accordingly, Legacy NeuBase's historical results of operations will replace the Company's (as defined below) historical results of operations for all periods prior to the Merger and, for all periods following the Merger, the results of operations of the combined company will be included in the Company's financial statements.

This annual report on Form 10-K relates to the Company's fiscal year ended September 30, 2019 and is therefore the Company's first periodic report that includes results of operations for the combined company, including Legacy NeuBase.

Unless the context otherwise requires, references to the "Company," the "combined company," "we," "our" or "us" in this report refer to NeuBase Therapeutics, Inc. and its subsidiaries, references to "NeuBase" refer to the Company following the completion of the Merger and references to "Ohr" refer to the Company prior to the completion of the Merger.

Except as otherwise noted, references to "common stock" in this report refer to common stock, par value $0.0001 per share, of the Company.

PART I.

Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K ("Form 10-K") contains "forward-looking statements" that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially and adversely from those expressed or implied by such forward-looking statements. The forward-looking statements are contained principally in Item 1—"Business," Item 1.A—"Risk Factors" and Item 7—"Management's Discussion and Analysis of Financial Condition and Results of Operations", but appear throughout the Form 10-K. Examples of forward-looking statements include, but are not limited to our expectations, beliefs or intentions regarding our potential product offerings, business, financial condition, results of operations, strategies or prospects and other matters that do not relate strictly to historical facts or statements of assumptions underlying any of the foregoing. These statements are often identified by the use of words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "ongoing," "opportunity," "plan," "potential," "predicts," "seek," "should," "will," or "would," and similar expressions and variations or negatives of these words. These forward-looking statements are based on the expectations, estimates, projections, beliefs and assumptions of our management based on information currently available to management, all of which are subject to change. Such forward-looking statements are subject to risks, uncertainties and other factors that are difficult to predict and could cause our actual results and the timing of certain events to differ materially and adversely from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed under Item 1.A—"Risk Factors" in this Form 10-K. Furthermore, such forward-looking statements speak only as of the date of this Form 10-K. We undertake no obligation to update or revise publicly any forward-looking statements to reflect events or circumstances after the date of such statements for any reason, except as otherwise required by law.

ITEM 1. BUSINESS

Overview

NeuBase Therapeutics, Inc. (the "Company", "we", "us" and "our") is a biotechnology company focused on developing next generation therapies to treat rare genetic diseases and cancers caused by mutant genes. Given that perhaps every human disease has a genetic component, we believe that our differentiated platform technology has the potential for broad impact.

Mutated proteins resulting from errors in deoxyribonucleic acid ("DNA") sequences cause many rare genetic diseases and cancer. DNA in each cell of the body is transcribed into pre-RNA, which is then processed (spliced) into mRNA which is exported into the cytoplasm of the cell and translated into protein. This is termed the "central dogma" of biology. Therefore, when errors in a DNA sequence occur, they are propagated to RNAs and can become a damaging protein.

The type of therapies that we are developing are termed antisense oligonucleotide therapies ("ASOs"). ASOs are short single strands of nucleic acids (traditionally thought of as single stranded ribonucleic acid ("RNA") molecules) which will bind to defective RNA targets in cells and inhibit their ability to be translated into defective proteins.

We believe we are a leader in the discovery and development of the class of RNA-targeted ASO drugs called peptide nucleic acids ("PNAs"). Our proprietary gamma Peptide-nucleic acid AnTisense OLigonucleotide ("PATrOL™") platform has the potential to provide a more efficient discovery of drug product candidates than traditional methods, potentially transforming the treatment paradigm for people affected by rare genetic diseases and cancer.

The PATrOL™ platform allows for a more efficient discovery of drug product candidates because of manufacturing consistency and because we are not constrained by folded regions of the target RNA molecule (secondary structures). The peptide backbone of our ASOs is rigid, and once linked together to form a series of backbone subunits, forms a single pre-organized structure. At a more detailed level, each subunit of the peptide backbone has only a single chiral center – a point in the chemical structure where the conformation of the backbone could fluctuate – and this chiral center is locked into one conformation and thus pre-organized to form only a single conformation or stereoisomer. A stereoisomer is a term used in the ASO therapeutics field to mean a string of backbone subunits (usually sugars or modified sugars) with nuclear bases attached that are linked together into a specific sequence that matches (complements) the target sequence, but because of the nature of the backbone subunits used, the drug assumes various conformations often with varying affinity for the target sequence. These stereoisomers often require a manufacturing step to purify the heterogeneous mixture of conformations into a more homogenous mixture or even a single conformation of the drug in order to obtain the hoped-for therapeutic effect. Our PNAs assume only a single conformation with any constellation of nuclear bases added to the backbone or any oligomer length. This backbone also has a neutral charge, as opposed to the negatively charged backbones of DNA and RNA. This neutral charge allows our ASO to open up RNAs which are folded upon themselves and bind to their target sequence. This potentially accelerates identification of drug candidates which have the desired activity.

In addition to the backbone conformational purity that allows for a more efficient discovery of drug product candidates, we have a kit of proprietary bi-facial or bi-specific nucleotides (traditional nucleotides only have a single binding face and thus are restricted to only binding single-stranded RNA targets), which can be used in various combinations to access RNA secondary structures (double-stranded RNA targets which are folded upon themselves) such as hairpins. This allows us to access regions of the target transcript that may be unique in secondary structure to allow enhanced selectivity for the target (mutant) RNA vs. the normal RNA. Enhanced selectivity for mutant RNAs vs. normal RNAs is critical as normal RNAs are generally required for effective functioning of the cell. These bi-specific nucleotides can potentially also target genomic loci (specific, fixed position on a chromosome where a particular gene or genetic marker is located) and microRNAs (small non-coding RNA molecule) in their double stranded form.

In addition to the backbone and modified nuclear bases, the platform toolkit includes linker technology which, when added to both ends of the PNAs, allow cooperative binding between individual drug molecules once they are engaged with the target RNA to form longer and more tightly bound drugs.

The final component of the platform is a chemical moiety, which is used to decorate the peptide backbone in a proprietary manner and allows the PNAs to penetrate cell membranes and distribute throughout the body when administered systemically.

This toolkit of components forms the PATrOL™ platform and allows us to manufacture genome and transcript-specific PNAs for screening against targets of interest.

We are currently focused on therapeutic areas in which we believe our drug candidates will provide the greatest benefit with a significant market opportunity and intend to utilize our technology to build out a pipeline of custom designed therapeutics for additional high-value disease targets. We are developing several preclinical programs using our PATrOL™ platform, including: NT0100, targeted at Huntington's Disease ("HD"), a repeat expansion disorder; and NT0200, targeted at type 1 myotonic dystrophy ("DM1"). Preclinical studies are being conducted to evaluate both the PATrOL™ platform technology broadly, as well as our program candidates in the areas of pharmacokinetics and pharmacodynamics, and we expect to report the results from those studies beginning in the first calendar quarter of 2020 and in the second calendar quarter of 2020. In addition, we plan to continue developing our emerging pipeline of other assets that target primary and secondary RNA structure and genomic DNA, which may afford us a unique market advantage across a variety of rare diseases and oncology targets.

Using our PATrOL™ platform, we believe we can create ASOs that have distinct potential advantages over other chemical entities currently in the market or in development for gene silencing applications. These potential advantages include, among others: a backbone that has only one chiral center and thus forms only one stereoisomer; the ability of the PNA backbone to intercalate (insert into), open up secondary (RNA folded upon itself) and tertiary structures (RNA molecules that interact with other RNA molecules in the cell) and bind within these double-stranded RNAs in a highly selective manner; a proprietary set of engineered nuclear bases to increase selectivity to specific target sequences including secondary and tertiary structures that has been licensed exclusively from Carnegie Mellon University ("CMU"); technology to allow self-assembly of our small gamma peptide-nucleic acid ("gamma-PNA") at the RNA target to increase selectivity, which has been licensed exclusively from CMU; the ability to modulate cell permeability and be broadly distributed across the body when administered systemically; the lack of innate or acquired immune responses of similar gamma-PNAs in preclinical models; and potential for low toxicity based on previous *in vivo* studies in rodent models. With these advantages, we believe our PATrOL™ platform-enabled therapies can potentially address a multitude of rare genetic diseases and cancer, among other indications.

Business Strategy

We employ a rational approach to selecting disease targets, considering many scientific, technical, business and indication-specific factors before choosing each indication. We intend to build a diverse portfolio of drugs custom-designed to treat a variety of health conditions, with an emphasis on rare genetic diseases and cancer. A key component of this strategy is continuing to improve the scientific understanding of our platform technology and programs, including how various components of our platform technology perform, and our drug candidates impact the biological processes of the target diseases, so that we can utilize this information to reduce risk in our future programs and indications. In addition, with our expertise in discovering and characterizing novel antisense drugs, we believe that our scientists can optimize the properties of our PATrOL™-enabled drug candidates for use with particular targets that we determine to be of high value.

The depth of our knowledge and expertise with gamma-PNA, bifacial nucleotides, engineered nucleotides, genetics and genomics and therapeutic development of first-in-class modalities provides potential flexibility to determine the optimal development and commercialization strategy to maximize the near and longer-term value of our drug candidates.

We have distinct partnering strategies that we plan to employ based on the specific drug candidate, therapeutic area expertise and resources potential partners may bring to a collaboration. For some drug candidates, we may choose to develop and, if approved, commercialize them ourselves or through our affiliates. For other drug candidates, we may form single or multi asset partnerships leveraging our partners' global expertise and resources needed to support large commercial opportunities.

Industry Segment Background

Rare Genetic Diseases

Globally, there are thousands of genetic diseases, most of which lack any therapeutic options. In addition, rare genetic diseases are often particularly severe, debilitating or fatal. Traditionally, therapeutic development for each rare genetic disorder has been approached with a unique strategy, which is inefficient, as there are thousands of diseases that need treatment solutions. The collective population of people with rare diseases stands to benefit profoundly from the emergence of a scalable and modular treatment development platform that allows for a more efficient discovery of drug product candidates to address these conditions cohesively.

Mutated proteins resulting from errors in deoxyribonucleic acid ("DNA") sequences cause many rare genetic diseases and cancer. DNA in each cell of the body is transcribed into pre-RNA, which is then processed (spliced) into mRNA which is exported into the cytoplasm of the cell and translated into protein. This is termed the "central dogma" of biology. Therefore, when errors in a DNA sequence occur, they are propagated to RNAs and can become a damaging protein. ASOs can inactivate target RNAs before they can produce harmful proteins by binding them in a sequence-specific manner, which can potentially delay disease progression or even eliminate genetic disease symptoms. ASOs designed to target known disease-related mutant RNA sequences could potentially address any dominantly inherited genetic disease caused by a single genetic mutation. Similarly, applications in modifying splicing of pre-RNA in the nucleus of the cell could be developed to exclude damaging exons from the final mRNA product. We also believe that given the ability of PNAs to insert into double stranded DNA and RNA targets, we can potentially pursue the development of drug candidates that target these types of nucleic acid sequences uniquely.

We believe the breadth of the PATrOL™ platform gives us the ability to potentially address thousands of inherited genetic diseases. The technology may also allow us to target and inactivate gain-of-function mutations by sequestering excess transcripts, and by inactivating transcripts with change-of-function mutations in them (vs. their wild-type or normal counterparts). The technology may also allow us to address targets in recessive disease and haploinsufficiencies by altering splicing to remove damaging exons/mutations. Various fields of use are available, including in oncology by reducing expression of activated oncogenes or modifying gene regulation by targeting microRNAs, for example, in complex genetic disease where subtle gene variants predispose to downstream diseases together with environmental triggers, or potentially in genome editing.

ASO Therapies

ASO therapies have been in development for several decades and are largely comprised of chemically modified, short-length RNA or DNA strands, commonly known as oligonucleotides. Oligonucleotides are comprised of a sequence of nucleotides—the building blocks of RNA and DNA—that are linked together by a backbone of chemical bonds. In nucleic acid molecules that have not been modified for therapeutic use, the nucleotides are linked by phosphodiester ("PO") bonds. Such unmodified nucleic acid molecules are unsuitable for use as therapeutics, because they are rapidly degraded by enzymes called nucleases which are widely distributed in the human body, are rapidly cleared by the kidneys and are taken up poorly by targeted cells. The industry has employed chemical modifications of the nucleotides and PO bonds that improve the stability, biodistribution and cellular uptake of nucleic acid therapeutics.

Challenges of Historical ASOs

ASOs can be highly specific to a singular RNA sequence, decreasing the chance of potentially toxic off-target effects. When designed properly, ASOs target exactly one mutated RNA sequence, corresponding directly to the genetic disorder of interest. Because they are targeted selectively to one sequence, optimally constructed ASOs do not target any additional genes and thus potentially reduce the likelihood of adverse events or side effects. While they have great potential, in practice, the current generation of ASOs is constrained by several factors intrinsic to their composition, including some or all of the following factors:

- they are not designed for optimal cell permeability, requiring them to be delivered at high concentrations or using other modalities that lead to other therapeutic and development challenges;
- they fail to demonstrate consistently broad tissue distribution throughout the body, often localizing predominantly to the liver when delivered systemically;
- they do not cross the blood-brain barrier, so they cannot access the central nervous system to address neurological disease without being delivered directly to the central nervous system via intrathecal injection;
- they can self-aggregate, leading to potential toxic accumulation of the drug and thus possible safety issues; and
- because natural oligonucleotides are recognized by enzymes throughout the body, they are subject to degradation before they can take effect, and thus others have had to extensively modify backbones resulting in immunological activation and challenges in manufacturing.

Peptide Nucleic Acids and Janus Bases

Details on PNAs were first published in 1991 by Peter Nielson, Michael Egholm and Ole Buchardt (Nielsen PE, Egholm M, Berg RH, Buchardt O. (1991) Sequence-selective recognition of DNA by strand displacement with a thymine-substituted polyamide. *Science*. 254 (5037): 1497–500). While these PNAs were shown to be able to bind nucleic acid strands in a sequence specific manner, this effect was not possible with targets comprised of both purines and pyrimidines. These first PNAs were also not water soluble, could not pass across plasma membranes, and self-aggregated, leading to potential toxic accumulation of the drug and thus possible safety issues. Based on this early data, the PNA backbone was modified at both the alpha positions to add conformational homogeneity enabling binding with mixed purine/pyrimidine natural nuclear base targets and additionally to allow water solubility. In 1996, Neil Branda, Guido Kurtz and Jean-Marie Lehn published "JANUS WEDGES: a new approach towards nucleobase-pair recognition" in the journal Chemical Communications. These bifacial nuclear bases had the potential to open a double helix and bind to both strands at a genomic locus in a "triad" motif utilizing the maximum number of Watson-Crick interactions. An issue with these early bi-facial nucleotides was that they were not uniform in their size and thus could not be used together on a peptide backbone to achieve the potential of binding both faces of an open DNA (or RNA) double helix.

PATrOL™ Technology Platform

Backbone technology: The PATrOL™ platform represents a next-generation gene silencing technology that we believe has the potential to significantly improve upon standard ASO techniques by combining the specificity of antisense approaches with the intracellular penetration and broad organ distribution capabilities of small molecule therapeutics. We are developing ASO therapies using our modular PATrOL™ platform. Our PATrOL™-enabled therapies act by binding to the mutant pre-RNA or messenger RNA ("mRNA") primary sequence (or secondary or tertiary conformations) to prevent translation by ribosomes into mutant proteins or otherwise eliminate a pathogenic feature of the mutant transcript. Unlike other ASOs, which have a sugar backbone or a chemically modified sugar backbone, our PATrOL™-enabled therapies are designed with a peptide backbone. Some of the potential advantages of using a peptide backbone include:

- the peptide backbone only has two stereoisomers (which can be selected with a single chemical modification at the chiral center), making it conformationally stable and enabling our approach to be modular by swapping in nuclear bases of interest;
- the peptide backbone is of neutral charge, thus facilitating the potential to intercalate (open up and insert) into double-stranded DNA and RNA hairpins, which we believe provides a unique advantage relative to other ASO chemistry in that its enables targetable "real estate" and also allows designs based on primary sequence that are not prohibited by secondary structures; and
- PATrOL™-enabled drugs are pre-organized into a right-handed helical conformation which meshes with double-stranded RNA molecules (namely hairpins) and thus have a higher potential binding affinity; and
- PATrOL™-enabled therapeutic candidates can target tissues throughout the body (due to the proprietary active moieties coupled to the protein backbone of the PNAs as described above) and are stable in circulation due to resistance against degradation as shown in previous studies with similar gamma-PNAs (Demidov VV, Potaman VN, Frank-Kamenetskii MD, Egholm M, Buchard O, Sönnichsen SH, Nielsen PE. (1994) Stability of peptide nucleic acids in human serum and cellular extracts. Biochem Pharmacol. 48(6):1310-3; McMahon BM, Mays D, Lipsky J, Stewart JA, Fauq A, Richelson E. Pharmacokinetics and tissue distribution of a peptide nucleic acid after intravenous administration. Antisense Nucleic Acid Drug Dev. 2002 Apr;12(2):65-70

Targeting technology: In early preclinical studies, our PATrOL™-enabled therapeutic candidates have shown potential advantages over the existing generation of ASOs. We believe that chief among these advantages are cell permeability and broad tissue distribution which have been demonstrated in early preclinical studies. These advantages would allow our PATrOL™ therapeutic candidates to potentially address a wide range of disorders affecting various organs and tissues with systemic or local administration.

The chemistry that we have licensed from CMU includes proprietary modifications to the peptide backbone to include an active moiety, which has been shown to be able to deliver payloads into cells through a process that appears to be endosome-independent, termed "active translocation." The preclinical studies that we reference, and which are the genesis of a medicinal chemistry process by the academics at CMU over the course of more than a decade of research, were published in a peer reviewed publication in 1999 by Steven Dowdy's team (Schwarze SR, Ho A, Vocero-Akbani A and Dowdy SF. (1999) *In Vivo* Protein Transduction: Delivery of a Biologically Active Protein into the Mouse. 285: 1569-1572). These preclinical data describe how the active moiety can traffic a payload of 120kD not only into most tissues, but also across the blood-brain barrier and into the cell bodies of neurons through all regions of the brain. In 2006, a team at CMU was the first to couple a similar active moiety to the peptide backbone of PNAs and show penetration through cell membranes (Dragulescu-Andrasi A, Rapireddy S, He G, Bhattacharya B, Hyldig-Nielsen JJ, Zon G, Ly DH. (2006) Cell-permeable peptide nucleic acid designed to bind to the 5'-untranslated region of E-cadherin transcript induces potent and sequence-specific antisense effects. *J Am Chem Soc.* 128(50):16104-12.).

Nucleotide technology: With our proprietary modular technology, we are capable of designing therapies with a peptide backbone onto which are coupled natural nuclear bases. Natural nuclear bases are commercially available. The peptide backbone subunits, each coupled to the proprietary active moiety, are manufactured by us and/or our suppliers. The natural nuclear bases are then coupled to the cell-permeable peptide backbone subunit to form a "monomer." In addition to being able to create these cell-permeable broadly distributed monomers that contain natural nuclear bases, we have licensed proprietary engineered nuclear bases (including bi-specific "Janus" bases) exclusively from CMU which can also be coupled to cell-permeable peptide backbone subunits. With these cell permeable monomers forming the basis of the platform, they can be linked together to form oligomers of any sequence composition, which can target primary RNA sequences as well as secondary RNA structures. A key attribute of the peptide backbone is that it is pre-organized chemically to form a rigid backbone (see discussion above). We believe that the modular components (i.e. the "monomers") together with the lack of chirality in the backbone makes the platform highly scalable for manufacturing purposes, thus enabling a more efficient discovery of drug product candidates for mutant gene silencing than traditional methods.

We believe we are the first and only company to successfully create Janus bases, engineered nucleic acids that target double-stranded RNA and potentially DNA by engaging both strands at once. The concept of Janus bases was first conceived nearly two decades ago but had not yet been realized due to the difficulty in chemical process development and the re-engineering required to allow the bifacial bases to have equal size – key considerations in creating tightly binding triple helices (or triads). A team of scientists, including our director of chemistry, has co-invented 16 different Janus bases to interface with every possible combination of 16 canonical and non-canonical nucleobase pairs that could occur in target RNA. Janus bases can be combined in various combinations to bind in a sequence-specific manner to secondary and tertiary RNA structures, whereas traditional antisense therapies generally cannot, and thus many sequences have heretofore not been targetable. This gives us the ability to expand the applicability of antisense therapies beyond their current capabilities as our candidates are not limited to regions of RNA that are free of secondary structure and thus potentially opens up a multitude of additional sequence targets. Our approach can also potentially be utilized for DNA therapeutics, such as gene editing, gene regulation and liquid biopsy diagnostics.

We have licensed proprietary technology from CMU, which comprises the modular elements of the PATrOL™ platform, including gamma-PNAs with a series of backbone modifications, such as with the proprietary active moieties critical for cell permeability in combination with exclusively licensed chemically engineered bifacial nucleotides against not only canonical base pairs (A-T or C-G hydrogen bonding), but also non-canonical binding, which allows targeting of RNA hairpins where the double-stranded RNA cannot bind to itself due to a mismatch, but that mismatch can be bound and stabilized by the non-canonical bifacial nucleotide. The elegance of this approach is the combination of the non-charged peptide backbone that does not cause repulsion when near a DNA or RNA negatively charged double helix with the proprietary bifacial nucleotides of uniform size. This combination is particularly powerful at the RNA level in addressing RNA hairpins with non-canonical bases to stabilize them and potentially eliminate the ability of target transcripts to be translated. The following **Figure 1** illustrates the concept of how our chemically engineered bifacial nuclear bases tethered to a peptide backbone can intercalate into the double helix of double-stranded RNA and assume a stable and sterically appropriate triple helix. The technology was developed over the course of almost a decade, and we believe it is unique to us, allowing us to target RNA secondary structures either by opening them up via our gamma-PNA technology to bind in a primary sequence-specific manner or by intercalating into secondary (or potentially even tertiary) structures, thus allowing sequence-specific selectivity of targets that have been largely not addressable to competing RNA silencing technologies.

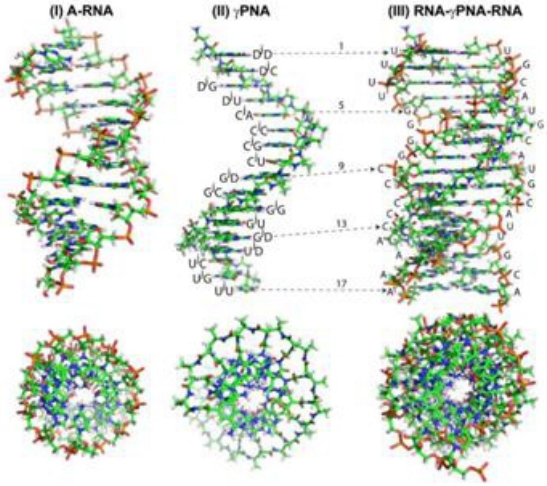

Figure 1. Simulations of a bifacial Janus base binding to an RNA duplex containing the corresponding base-pairs illustrating the pre-organized right-handed structure of the gamma-PNA and the steric uniformity of the bifacial nucleotides.

While traditional ASOs can be long (*i.e.*, 16-mers or longer), PATrOL™-enabled therapies can be as small as a 3-mer gamma-PNA due to the Janus bases, allowing them to better reach target tissue and disseminate evenly within cells. As a result of their capability to disperse through many body tissues, PATrOL™-enabled therapies have the potential to address whole-body symptoms of diseases that manifest in multiple organ systems.

Product Pipeline

Huntington's Disease

HD is a devastating rare neurodegenerative disorder. After onset, symptoms such as uncontrolled movements, cognitive impairments and emotional disturbances worsen over time. HD is caused by toxic aggregation of mutant huntingtin protein, leading to progressive neuron loss in the striatum and cortex of the brain. The wildtype huntingtin gene (*HTT*) has a region in which a three-base DNA sequence, CAG, is repeated many times. When the DNA sequence CAG is repeated 26 or fewer times in this region, the resulting protein behaves normally. While the wildtype function of *HTT* is largely uncharacterized, the protein is known to be essential for normal brain development. When the DNA sequence CAG is repeated 40 times or more in this region, the resulting protein becomes toxic and causes HD. Every person has two copies, or alleles, of the *HTT*. Only one of the alleles (the "mutant" allele) needs to bear at least 40 CAG repeats for HD to occur. HD is one of many known repeat expansion disorders, which are a set of genetic disorders caused by a mutation that leads to a repeat of nucleotides exceeding the normal threshold. Current therapies for patients with HD can only manage individual symptoms. There is no approved therapy that has been shown to delay or halt disease progression. There are approximately 30,000 symptomatic patients in the U.S. and more than 200,000 at-risk of inheriting the disease.

NT0100 Program - PATrOL™ Enabled PNA for Huntington's Disease

The PATrOL™ platform has the potential to address many dominantly inherited genetic diseases. We will be initially focused on HD, a fatal rare genetic repeat expansion disorder with no viable treatment options.

One especially important advantage of the PATrOL™ platform that makes it promising for the treatment of repeat expansion disorders like HD is the ability of our small ASOs to potentially self-assemble within an RNA hairpin. As the number of repeats increases, the PATrOL™ oligonucleotides bind more tightly to each other and the mutant RNA. This allows our therapies to potentially inactivate mutant *HTT* mRNA before it can be translated into harmful protein via selective binding to the expanded CAG repeats while leaving the normal *HTT* mRNA largely unbound to drug and producing functional protein. Achieving mutant allele selectivity would be a key advantage for any RNA-based approach aiming to treat HD. The PATrOL™-enabled NT0100 program is currently in preclinical development for the treatment of HD.

NT0200 Program- PATrOL™ Enabled gamma-PNA for Myotonic Dystophy Type 1

Our pipeline also contains a second near-term, potentially transformative medicine, which we believe has significant potential for a different severe and rare trinucleotide repeat disease, DM1. Myotonic dystrophy type 1 (DM1) is a multisystem disorder that primarily affects skeletal and smooth muscle. DM1 is caused by expansion of a CTG trinucleotide repeat in the noncoding region of the *DMPK* gene, which captures and sequesters splice proteins. Sequestered splice proteins cannot then fulfill their normal functions. The diagnosis of DM1 is suspected in individuals with characteristic muscle weakness and is confirmed by molecular genetic testing of *DMPK*. CTG repeat length exceeding 34 repeats is abnormal. Molecular genetic testing detects pathogenic variants in nearly 100% of affected individuals. It is estimated that the global prevalence of DM1 is 1:20,000 individuals. The clinical candidates in development target the DM1 expanded allele with PATrOL™-enabled drug candidates to disrupt and/or open the mutant hairpin and allow release of sequestered splice proteins.

Additional Indications

In addition, we are in the process of building an early stage pipeline of other therapies that focus on the unique advantages of our technology across a variety of rare diseases.

Intellectual Property

We have a strong intellectual property position behind our fundamental PATrOL™ technology that was developed at CMU. Our success depends, in part, on our ability to obtain patent protection for our product candidates in the United States and other countries. We have exclusively licensed patent applications, pursuant to our license agreement with CMU (the "CMU License Agreement"), protecting our platform for development and commercialization of oligonucleotide therapeutics. We will focus our resources on obtaining patents and filing new patent applications that drive value.

We have an exclusive license to patent applications pursuant to the CMU License Agreement that may provide exclusivity for product candidates in our pipeline and may provide exclusivity for our core technology. Our core technology patent applications are directed to chemically-modified nucleosides and peptide nucleic acids to form compounds of biological and clinical interest. We have exclusively licensed patent applications pursuant to the CMU License Agreement to cover 16 Janus bases and treatment of repeat expansion disorders using this technology.

Peptide Nucleic Acids containing Modified Nucleobases

We have exclusively licensed patent applications pursuant to the CMU License Agreement covering peptide nucleic acid oligomers containing modified nucleobases, which can be used as a basis for therapeutics. Nucleosides and chemically modified nucleosides are the basic building blocks of our drug development platform. Therefore, claims that cover an oligonucleotide incorporating one of our proprietary modified nucleosides may apply to a wide array of mechanisms of action and therapeutic targets. Our modified nucleobases may comprise a divalent nucleobase in sequence with several other divalent nucleobases to create a PNA.

We have filed patent applications in this category in the United States and pursuant to the Patent Cooperation Treaty.

Methods of Producing Peptide Nucleic Acids with Modified Nucleobases

We have exclusively licensed a patent (with an estimated expiration date of April 11, 2034) in the United States pursuant to the CMU License Agreement disclosing a method of manufacturing a peptide nucleic acid oligomer containing a modified nucleobase. We have exclusively licensed a provisional patent application (with an estimated expiration date of March 21, 2040) in the United States pursuant to the CMU License Agreement disclosing a method of synthesis of LH and RH gamma PNA monomers with on-resin sidechain functionalization.

Use of Peptide Nucleic Acids to Disrupt RNA Structure

We have exclusively licensed a provisional patent application (with an estimated expiration date of June 7, 2039) in the United States pursuant to the CMU License Agreement covering use of a peptide nucleic acid oligomer for disrupting a target RNA structure, to prevent translation of a target protein.

Use of Peptide Nucleic Acids to Treat Repeat Expansion Disorders

We have exclusively licensed patent applications (with an estimated expiration date of February 22, 2040) in the United States pursuant to the CMU License Agreement covering the use of a peptide nucleic acid oligomer for the treatment of repeat expansion disorders, including, for example, HD and DM1.

Patent Portfolio

As of January 7, 2020, we owned or in-licensed approximately 2 issued patents, which will expire in approximately 2034 without taking into account and possible patent term adjustments or extensions. As of January 7, 2020, we also owned or in-licensed approximately 13 patent applications, which if ultimately issued would expire as late as approximately 2040, based upon the potential expiration date of the last to expire of those patent applications without taking into account any possible patent term adjustments or extensions. As to the in-licensed patents and patent applications, they include 2 issued patents and 12 patent applications from CMU pursuant to the CMU License Agreement.

We plan to seek patent protection in significant markets and/or countries for each product to be developed. We also seek to maximize patent terms. In some cases, the patent term can be extended to recapture a portion of the term lost during the U.S. Food and Drug Administration (the “FDA”) regulatory review. The patent exclusivity period for a drug may deter generic drugs from entering the market. Patent exclusivity depends on a number of factors including initial patent term and available patent term extensions based upon delays caused by the regulatory approval process.

We also rely on trade secrets, proprietary know-how and continuing technological innovation to develop and maintain a competitive position in our field.

While we have obtained patents and have patent applications pending, the extent of effective patent protection in the United States and other countries is highly uncertain. No consistent policy addresses the breadth of claims allowed in or the degree of protection afforded under patents of medical and pharmaceutical companies. Patents we currently own or may obtain might not be sufficiently broad to protect us against competitors with similar technology. Any of our patents could be invalidated or circumvented.

The holders of competing patents could determine to commence a lawsuit against us and may even prevail in any such lawsuit. Litigation could result in substantial cost to and diversion of effort by us, which may harm our business. In addition, our efforts to protect or defend our proprietary rights may not be successful or, even if successful, may result in substantial cost to us.

License Agreement with Carnegie Mellon University

On December 17, 2018, we entered into the CMU License Agreement. Under the CMU License Agreement, CMU granted us an exclusive, worldwide right to the PATrOL™ technology, with 14 patents and patent applications describing composition of matter and uses of the platform. Our exclusive, worldwide right to the PATrOL™ technology is subject to CMU's right (which is exercisable only upon our written consent) to grant a non-exclusive license to a third party as a means of resolving disputes or to settle claims arising out of allegations that the licensed technology under the CMU License Agreement infringes upon the intellectual property rights of such third party.

As partial consideration for the license right, we issued and delivered to CMU 835,625 shares of our common stock, which constituted 8.2% of the then fully diluted shares of our common stock. Further, as partial consideration for the license right, we issued a warrant to CMU, exercisable only upon the earlier of (i) the day that we received cumulative capital funding or revenues equal to $2 million or (ii) 30 days prior to any change of control event that provides for the issuance of shares, for a number of shares of our common stock sufficient such that when added to the 835,625 shares of our common stock, CMU's holds in the aggregate an amount equal to 8.2% of the fully-diluted shares of our common stock; *provided*, *however*, that for purposes of calculating 8.2%, only the first $2 million of capital funding shall be considered in the determination of fully-diluted shares of our common stock. CMU exercised the warrant issued under the CMU License Agreement prior to the effective time of the Merger (as defined below) for an aggregate of 103,787 shares of our common stock. Under the CMU License Agreement, CMU has preemptive rights with respect to certain future sales of securities by us for capital-raising purposes, "piggyback" registration rights and co-sale rights with respect to certain resales of shares by our stockholders.

Pursuant to the CMU License Agreement, we paid CMU a one-time payment of approximately $54,000 for patenting and other intellectual property protection costs incurred by CMU prior to the effective date of the CMU License Agreement and relating to the licensed technology thereunder. Further, we must achieve certain milestones to demonstrate certain developments of the licensed product. We may obtain one 6-month extension to meet each milestone by making a nominal payment to CMU. Further, subject to certain conditions, we will pay to CMU royalties at a low single-digit percentage of aggregate annual net sales of licensed products and a percentage at the higher range of the bottom third of sublicensing fees.

The term of the CMU License Agreement concludes at the end of 20 years from its effective date or on the expiration date of the last-to-expire patent licensed, whichever comes later, unless otherwise terminated. The CMU License Agreement may be terminated (or the exclusivity of the license may be terminated) before the term due to customary payment default and fundamental change default provisions and failure of performance obligations. In addition, CMU may terminate the CMU License Agreement if we or our affiliates challenge the validity of the intellectual property licensed thereunder in a judicial or administrative proceeding. In the event we or our affiliates successfully challenge the validity of the intellectual property licensed thereunder, the royalties payable to CMU increase by a single digit percentage. We may terminate the CMU License Agreement upon payment of termination fees, the amounts of which depend on the date of such termination, but only if at the time of such termination, a licensed patent contains a valid claim. If not earlier terminated, at the expiration of the term, the rights and licenses granted to us by CMU survive in perpetuity, subject to our compliance with indemnification and dispute resolution obligations.

Manufacturing

We currently manufacture our starting materials using third-party suppliers and our research-scale final products both in-house and externally. We intend to rely on third parties for larger scale manufacturing going forward. We do not have any current contractual arrangements for the manufacture of commercial supplies of any of our product candidates that we may develop. We currently employ internal resources and third-party consultants to manage our manufacturing contractors.

Sales and Marketing

We have not yet defined our sales, marketing or product distribution strategy for any of our future product candidates. Our commercial strategy may include the use of strategic partners, distributors, a contract sale force, or the establishment of our own commercial and specialty sales force, as well as similar strategies for regions and territories outside the United States. We plan to further evaluate these alternatives when it approaches approval for the use of our product candidates for one or more indications.

Competition

The biotechnology industry is highly competitive and involves a high degree of risk. Potential competitors in the United States and worldwide are numerous and include pharmaceutical and biotechnology companies, educational institutions and research foundations. We compete with many of these companies who, either alone or with their strategic partners, have far greater experience, capital resources, research and technical resources, marketing experience, clinical trial experience, research and development staffs and facilities than we do. Some of our competitors may develop and commercialize products that compete directly with our product candidates, and they may introduce products to market earlier than our products or on a more cost-effective basis. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and also, in the future, to recruit clinical trial sites and subjects for our clinical trials.

We expect any products that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, price and the availability of reimbursement from government and other third-party payors. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are viewed as safer, more effective, more convenient or less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their competing products more rapidly than we may obtain approval for any of our product candidates, which could result in our competitors establishing a strong market position before we are able to enter the market.

There are currently no approved treatments available to slow the progression of HD. Based on publicly available information, Roche and Ionis have an investigational drug in Phase III clinical development, and several companies have ongoing clinical and preclinical programs targeting the underlying disease in HD, including Wave Life Sciences, LTD., Sangamo Biosciences, ProQR, Nuredis, uniQure, Spark Therapeutics (which was recently acquired by Roche) and Voyager Therapeutics. A number of other companies are developing drugs focused on treating the symptoms associated with HD, including Teva Pharmaceutical Industries (Phase II), Vaccinex (Phase II), Prana Biotechnology (Phase II), Omeros Corporation (Phase II), Stealth BioTherapeutics (Phase II) and Azevan Pharmaceuticals (Phase II), among others.

There are no disease-modifying treatments available for DM1. Based on review of the clinictrials.gov and clinicialtrialsregister.eu websites, AMO Pharmaceuticals reported results of a 16-patient non-randomized, clinical trial in congenital DM1 with tidegluseb, a thiazoledione that inhibits glycogen synthase kinase 3 beta, and is also currently initiating a 56 patient Phase II/III randomized, controlled study. Ionis conducted a Phase I/II trial of IONIS-DMPKRx in a randomized, controlled 48 patients with DM1 that did not demonstrate efficacy, and has since abandoned the indication. The Centre d'Etude des Cellules Souches (CECS), a non-commercial sponsor, is conducting a 40-patient clinical trial of metformin in DM1 in France. In addition to AMO Pharmaceuticals, Dyne, Vertex, Triplet Therapeutics, Expansion Therapeutics, and Nuredis are investigating agents to treat DM1.

Reverse Stock Split

On January 18, 2019, following a special meeting of our stockholders, our board of directors approved a one-for-twenty reverse stock split of our issued and outstanding shares of common stock (the "Reverse Stock Split"). On January 23, 2019, we filed with the Secretary of State of the State of Delaware a Certificate of Amendment to our Certificate of Incorporation to effect the Reverse Stock Split. Our common stock began trading on a split-adjusted basis when the market opened on February 4, 2019. As a result of the Reverse Stock Split, the outstanding common stock decreased from 56,466,428 shares of common stock, par value $0.0001 per share, to 2,829,248 shares of common stock, par value $0.0001 per share.

Unless otherwise noted, impacted amounts and share information included in the financial statements and notes thereto, and elsewhere in this Form 10-K have been retroactively adjusted for the Reverse Stock Split as if such Reverse Stock Split occurred on the first day of the first period presented. Certain amounts in the financial statements, the notes thereto, and elsewhere in this Form 10-K, may be slightly different than previously reported due to rounding of fractional shares as a result of the Reverse Stock Split.

Merger

On July 12, 2019, Ohr Pharmaceutical, Inc., a Delaware corporation ("Ohr"), completed a merger with NeuBase Therapeutics, Inc., a Delaware corporation ("Legacy NeuBase"), in accordance with the terms of the Agreement and Plan of Merger Reorganization entered into on January 2, 2019 (the "Merger Agreement"). Pursuant to the Merger Agreement, (i) a subsidiary of Ohr merged with and into Legacy NeuBase, with Legacy NeuBase (renamed as "NeuBase Corporation") continuing as a wholly-owned subsidiary of Ohr and the surviving corporation of the merger and (ii) Ohr was renamed as "NeuBase Therapeutics, Inc." (the "Merger"). At the closing of the Merger, each outstanding share of Legacy NeuBase's capital stock was converted into the right to receive 1.019055643 shares of the Company's common stock. Shares of the Company's common stock commenced trading on the Nasdaq Capital Market under the ticker symbol "NBSE" as of market open on July 15, 2019. The Company's previous ticker symbol was "OHRP".

Unless otherwise noted, impacted amounts and share information included in the financial statements and notes thereto, and elsewhere in this Form 10-K have been retroactively adjusted for the Merger as if such Merger occurred on the first day of the first period presented. Certain amounts in the financial statements, the notes thereto, and elsewhere in this Form 10-K, may be slightly different than previously reported due to rounding of fractional shares as a result of the Merger.

Pre-Merger Financing

On July 11, 2019, prior to the completion of the Merger, Legacy NeuBase completed transactions contemplated by certain financing agreements (the "Pre-Merger Financing") resulting in gross proceeds to Legacy NeuBase of approximately $9.0 million, consisting of (i) a private placement with certain accredited investors, whereby, among other things, Legacy NeuBase issued to such investors shares of Legacy NeuBase common stock for an aggregate purchase price of approximately $8.40 million (the "Legacy NeuBase Equity Financing") and (ii) the conversion of outstanding convertible notes of Legacy NeuBase with an aggregate principal amount of $600,000 (the "Legacy NeuBase Debt Financing"), which were automatically converted into Legacy NeuBase common stock immediately preceding the closing of the Legacy NeuBase Equity Financing at a conversion price equal to 90% of the purchase price per share of the Legacy NeuBase common stock issued in the Legacy NeuBase Equity Financing.

Post-Merger Financing

On July 12, 2019, we entered into a Securities Purchase Agreement with certain accredited investors, pursuant to which, among other things, we agreed to sell to the investors an aggregate of 1,538,462 shares of common stock at a purchase price of $3.25 per share for aggregate gross proceeds of $5.0 million (the "Post-Merger Financing"). On July 16, 2019, we completed the Post-Merger Financing and issued an aggregate of 1,538,462 shares of our common stock.

Legacy Pre-Merger Programs

As a result of the Merger, our going-forward operations will be primarily those of Legacy NeuBase. Pursuant to the Merger, we retained certain assets and technologies that were Ohr's assets and technologies before the consummation of the Merger. Despite our expectation that our primary operations will be those of Legacy NeuBase on a going-forward basis, we may choose to monetize legacy Ohr assets in the future. Previously, Ohr acquired the SKS Ocular 1 LLC sustained release technology, which was designed to develop best in class drug formulations for ocular disease (the "SKS Assets") and exclusive rights to an animal model for dry macular degeneration and rights to produce and use carboxyethylpyrrole ("CEP") for research, clinical and commercial applications (the "CEP Assets"). In September 2019, we terminated the licenses for the SKS Assets and the CEP Assets, as the Board determined there would be substantial costs associated with continuing to maintain such assets and attempts to monetize such assets would be a distraction to our management and other employees and an inefficient use of their time. We continue to retain an equity interest in DepYmed, Inc. ("DepYmed"), a joint venture that Ohr entered into with Cold Spring Harbor Laboratory in 2014. DepYmed is a preclinical stage company focused on Wilson's disease, Rett syndrome, and oncology applications. We also retain intellectual property which has been licensed to DepYmed and have no other ongoing obligations (monetary or otherwise) to DepYmed.

Governmental Regulation

Government authorities in the United States (including federal, state and local authorities) and in other countries, extensively regulate, among other things, the manufacturing, research and clinical development, marketing, labeling and packaging, storage, distribution, post-approval monitoring and reporting, advertising and promotion, pricing and export and import of pharmaceutical products, such as our product candidates. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Moreover, failure to comply with applicable regulatory requirements may result in, among other things, warning letters, clinical holds, civil or criminal penalties, recall or seizure of products, injunction, disbarment, partial or total suspension of production or withdrawal of the product from the market. Any agency or judicial enforcement action could have a material adverse effect on us.

Food and Drug Administration Regulation and Marketing Approval

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), and related regulations. Drugs are also subject to other federal, state and local statutes and regulations. Failure to comply with the applicable U.S. regulatory requirements at any time during the drug development process, approval process or after approval may subject an applicant to administrative or judicial sanctions and non-approval of product candidates. These sanctions could include the imposition by the FDA or an Institutional Review Board ("IRB") of a clinical hold on clinical trials, the FDA's refusal to approve pending applications or related supplements, withdrawal of an approval, untitled or warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, restitution, disgorgement, civil penalties or criminal prosecution. Such actions by government agencies could also require us to expend a large amount of resources to respond to the actions. Any agency or judicial enforcement action could have a material adverse effect on us.

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products.

These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, packaging, storage, distribution, record-keeping, approval, post-approval monitoring, advertising, promotion, sampling and import and export of our products. Our drug candidates must be approved by the FDA through the New Drug Application ("NDA") process before they may be legally marketed in the United States.

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

- completion of non-clinical laboratory tests, animal studies and formulation studies conducted according to good laboratory practice or other applicable regulations;
- submission of an Investigational New Drug application ("IND"), which allows clinical trials to begin unless the FDA objects within 30 days;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use or uses conducted in accordance with Good Clinical Practices ("GCPs"), which are international ethical and scientific quality standards meant to assure that the rights, safety and well-being of trial participants are protected, and to define the roles of clinical trial sponsors, administrators and monitors and to assure clinical trial data integrity;
- pre-approval inspection of manufacturing facilities and clinical trial sites; and
- FDA approval of an NDA, which must occur before a drug can be marketed or sold.

IND and Clinical Trials

Prior to commencing the first clinical trial, an IND, which contains the results of preclinical studies along with other information, such as information about product chemistry, manufacturing and controls and a proposed protocol, must be submitted to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA unless the FDA within the 30-day time period raises concerns or questions about the conduct of the clinical trial. In such a case, the IND sponsor must resolve any outstanding concerns with the FDA before the clinical trial may begin. A separate submission to the existing IND must be made for each successive clinical trial to be conducted during drug development. Further, an independent IRB for each site proposing to conduct the clinical trial must review and approve the investigational plan for any clinical trial before it commences at that site. Informed written consent must also be obtained from each trial subject. Regulatory authorities, including the FDA, an IRB, a data safety monitoring board or the sponsor, may suspend or terminate a clinical trial at any time on various grounds, including a finding that the participants are being exposed to an unacceptable health risk or that the clinical trial is not being conducted in accordance with FDA requirements.

For purposes of NDA approval, human clinical trials are typically conducted in sequential phases that may overlap:

- *Phase I* - The drug is initially given to healthy human subjects or patients in order to determine metabolism and pharmacologic actions of the drug in humans, side effects and, if possible, to gain early evidence on effectiveness. During Phase I clinical trials, sufficient information about the investigational drug's pharmacokinetics and pharmacologic effects may be obtained to permit the design of well-controlled and scientifically valid Phase II clinical trials.
- *Phase II* - Clinical trials are conducted to evaluate the effectiveness of the drug for a particular indication or in a limited number of patients in the target population to identify possible adverse effects and safety risks, to determine the efficacy of the drug for specific targeted diseases and to determine dosage tolerance and optimal dosage. Multiple Phase II clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase III clinical trials.
- *Phase III* - When Phase II clinical trials demonstrate that a dosage range of the drug appears effective and has an acceptable safety profile, and provide sufficient information for the design of Phase III clinical trials, Phase III clinical trials in an expanded patient population at multiple clinical sites may be undertaken. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to further evaluate dosage, effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug and to provide an adequate basis for product labeling and approval by the FDA. In most cases, the FDA requires two adequate and well-controlled Phase III clinical trials to demonstrate the efficacy of the drug in an expanded patient population at multiple clinical trial sites.
- *Phase IV* - The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These Phase IV clinical trials may be made a condition to be satisfied for continuing drug approval. The results of Phase IV clinical trials can confirm the effectiveness of a product candidate and can provide important safety information.

All clinical trials must be conducted in accordance with FDA regulations, GCP requirements and their protocols in order for the data to be considered reliable for regulatory purposes.

An investigational drug product that is a combination of two different drugs in the same dosage form must comply with an additional rule that requires that each component make a contribution to the claimed effects of the drug product. This typically requires larger studies that test the drug against each of its components. In addition, typically, if a drug product is intended to treat a chronic disease, as is the case with some of our product candidates, safety and efficacy data must be gathered over an extended period of time, which can range from six months to three years or more. Government regulation may delay or prevent marketing of product candidates or new drugs for a considerable period of time and impose costly procedures upon our activities.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial, is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

The NDA Approval Process

In order to obtain approval to market a drug in the United States, a marketing application must be submitted to the FDA that provides data establishing to the FDA's satisfaction the safety and effectiveness of the investigational drug for the proposed indication. Each NDA submission requires a substantial user fee payment (exceeding $2.5 million in fiscal year 2019) unless a waiver or exemption applies. The application includes all relevant data available from pertinent non-clinical studies, or preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators that meet GCP requirements.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase II clinical trials, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the end-of-Phase II clinical trials meetings to discuss their Phase II clinical trials results and present their plans for the pivotal Phase III registration trial that they believe will support approval of the new drug.

Concurrent with clinical trials, companies usually complete additional preclinical safety studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for the NDA sponsor's manufacturing the product in compliance with Current Good Manufacturing Practice ("cGMP") requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drugs. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf-life.

The results of drug development, non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. It may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. The FDA has 60 days from its receipt of an NDA to conduct an initial review to determine whether the application will be accepted for filing based on the FDA's threshold determination that the application is sufficiently complete to permit substantive review. If the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA has agreed to specific performance goals on the review of NDAs and seeks to review standard NDAs within 12 months from submission of the NDA. The review process may be extended by the FDA for three additional months to consider certain late submitted information or information intended to clarify information already provided in the submission. After the FDA completes its initial review of an NDA, it will communicate to the sponsor that the drug will either be approved, or it will issue a complete response letter to communicate that the NDA will not be approved in its current form and inform the sponsor of changes that must be made or additional clinical, non-clinical or manufacturing data that must be received before the application can be approved, with no implication regarding the ultimate approvability of the application or the timing of any such approval, if ever. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two to six months depending on the type of information included. The FDA may refer applications for novel drug products or drug products that present difficult questions of safety or effectiveness to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical sites to assure compliance with GCP regulations. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, it typically will outline the deficiencies and often will request additional testing or information. This may significantly delay further review of the application. If the FDA finds that a clinical site did not conduct the clinical trial in accordance with GCP regulations, the FDA may determine the data generated by the clinical site should be excluded from the primary efficacy analyses provided in the NDA. Additionally, notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The FDA may require, or companies may pursue, Phase IV clinical trials, which are additional clinical trials performed after a product is approved. Phase IV clinical trials may be made a condition to be satisfied for continuing drug approval. The results of Phase IV clinical trials can confirm the effectiveness of a product candidate and can provide important safety information. In addition, the FDA now has express statutory authority to require sponsors to conduct post-marketing trials to specifically address safety issues identified by the agency.

The FDA also has authority to require a Risk Evaluation and Mitigation Strategy ("REMS"), from manufacturers to ensure that the benefits of a drug outweigh its risks. A sponsor may also voluntarily propose a REMS as part of the NDA submission. The need for a REMS is determined as part of the review of the NDA. Based on statutory standards, elements of a REMS may include "dear doctor letters," a medication guide, more elaborate targeted educational programs, and in some cases elements to assure safe use ("ETASU"), which is the most restrictive REMS. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. These elements are negotiated as part of the NDA approval, and in some cases if consensus is not obtained until after the "review date" set forth under the Prescription Drug User Fee Act of 1992, as amended, the approval date may be delayed. Once adopted, REMS are subject to periodic assessment and modification.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Even if a product candidate receives regulatory approval, the approval may be limited to specific disease states, patient populations and dosages, or might contain significant limitations on use in the form of warnings, precautions or contraindications, or in the form of onerous risk management plans, restrictions on distribution or post-marketing trial requirements. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delay in obtaining, or failure to obtain, regulatory approval for our products, or obtaining approval but for significantly limited use, would harm our business. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

Orphan Designation and Exclusivity

The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States and there is no reasonable expectation that the cost of developing and making the drug for this type of disease or condition will be recovered from sales in the United States.

Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical study costs, tax advantages, and user-fee waivers. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. In addition, the first NDA or Biologics License Application ("BLA") applicant to receive orphan drug designation for a particular drug is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years in the United States, except in limited circumstances. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Our initial two programs are targeting orphan indications.

The Hatch-Waxman Amendments

Under the Drug Price Competition and Patent Term Restoration Act of 1984, as amended, commonly known as the Hatch-Waxman Amendments, a portion of a product's U.S. patent term that was lost during clinical development and regulatory review by the FDA may be restored. The Hatch-Waxman Amendments also provide a process for listing patents pertaining to approved products in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) and for a competitor seeking approval of an application that references a product with listed patents to make certifications pertaining to such patents. In addition, the Hatch-Waxman Amendments provide for a statutory protection, known as non-patent exclusivity, against the FDA's acceptance or approval of certain competitor applications.

Patent Term Restoration

Patent term restoration can compensate for time lost during drug development and the regulatory review process by returning up to five years of patent life for a patent that covers a new product or its use. This period is generally one-half the time between the effective date of an IND (falling after issuance of the patent) and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application, provided the sponsor acted with diligence. Patent term restorations, however, cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended and the extension must be applied for prior to expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed by the NDA holder listed in the drug's application or otherwise are then published in the FDA's Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application ("ANDA"). An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical studies or clinical trials to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a Section VIII statement certifying that its proposed ANDA label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

An applicant submitting an NDA under Section 505(b)(2) of the FDCA (a "Section 505(b)(2) NDA"), which permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference, is required to certify to the FDA regarding any patents listed in the Orange Book for the approved product it references to the same extent that an ANDA applicant would.

Market Exclusivity

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a Section 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a Paragraph IV certification. The FDCA also provides three years of marketing exclusivity for an NDA, a Section 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the non-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Post-Marketing Requirements.

Following approval of a new product, a pharmaceutical company and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting to the applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet, including social media. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses. Modifications or enhancements to the product or its labeling or changes of the site of manufacture are often subject to the approval of the FDA and other regulators, who may or may not grant approval, or may include in a lengthy review process.

Prescription drug advertising is subject to federal, state and foreign regulations. In the United States, the FDA regulates prescription drug promotion, including direct-to-consumer advertising. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Any distribution of prescription drug products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act of 1987, as amended, a part of the FDCA.

In the United States, once a product is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that products be manufactured in specific, approved facilities and in accordance with cGMP. NeuBase relies, and expects to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. cGMP regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. NDA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such product or may result in restrictions on a product, manufacturer, or holder of an approved NDA, including, among other things, recall or withdrawal of the product from the market.

The FDA also may require post-marketing testing, also known as Phase IV testing, REMS to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, untitled or warning letters from the FDA, mandated corrective advertising or communications with doctors, withdrawal of approval, and civil or criminal penalties, among others. Newly-discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products in development.

Reimbursement, Anti-Kickback and False Claims Laws and Other Regulatory Matters

In the United States, the research, manufacturing, distribution, sale and promotion of drug products and medical devices are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services ("CMS"), other divisions of the U.S. Department of Health and Human Services (*e.g.*, the Office of Inspector General), the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, state Attorneys General and other state and local government agencies. For example, sales, marketing and scientific/educational grant programs must comply with the federal Anti-Kickback Statute, the federal False Claims Act, the privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, and similar state laws. Pricing and rebate programs must comply with the Medicaid Drug Rebate Program requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The Medicare Modernization Act ("MMA") established the Medicare Part D program ("Part D") to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Unlike Medicare Part A (hospital insurance) and Part B (medical insurance), Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for product candidates for which NeuBase receives regulatory approval. However, any negotiated prices for our product candidates covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-government payors.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of our product candidates, if any such product or the condition that it is intended to treat is the subject of a clinical trial. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates, if approved. If third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our product candidates after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our product candidates on a profitable basis.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be priced significantly lower than in the United States.

As noted above, in the United States, we are subject to complex laws and regulations pertaining to healthcare "fraud and abuse," including, but not limited to, the federal Anti-Kickback Statute, the federal False Claims Act, and other state and federal laws and regulations. The federal Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer, or a party acting on its behalf, to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce the referral of business, including the purchase, order or prescription of a particular drug, or other good or service for which payment in whole or in part may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, many states have adopted laws similar to the federal Anti-Kickback Statute. Some of these state prohibitions apply to the referral of patients for healthcare services reimbursed by any insurer, not just federal healthcare programs such as Medicare and Medicaid. Due to the breadth of these federal and state anti-kickback laws, the absence of guidance in the form of regulations or court decisions and the potential for additional legal or regulatory change in this area, it is possible that our future sales and marketing practices or our future relationships with medical professionals might be challenged under anti-kickback laws, which could harm us. Because we intend to commercialize product candidates that could be reimbursed under a federal healthcare program and other governmental healthcare programs, we plan to develop a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and program requirements to which we will or may become subject.

The federal False Claims Act prohibits anyone from knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services. Although we would not submit claims directly to payors, manufacturers 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 or promoting a product off-label. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our product candidates, and the sale and marketing of our product candidates, are subject to scrutiny under this law. For example, pharmaceutical companies have been found liable under the federal False Claims Act in connection with their off-label promotion of drugs. Penalties for a federal False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between $11,181 and $22,363 for each separate false claim, the potential for exclusion from participation in federal healthcare programs and, although the federal False Claims Act is a civil statute, conduct that results in a federal False Claims Act violation may also implicate various federal criminal statutes. If the government were to allege that we were, or convict us of, violating these false claims laws, we could be subject to a substantial fine. In addition, private individuals have the ability to bring actions under the federal False Claims Act and certain states have enacted laws modeled after the federal False Claims Act.

There are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. In addition, as discussed below, a similar federal requirement requires manufacturers to track and report to the federal government certain payments made to physicians and teaching hospitals in the previous calendar year. These laws may affect our sales, marketing and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state, and soon federal, authorities.

The failure to comply with regulatory requirements subjects companies to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a company to enter into supply contracts, including government contracts.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (1) changes to our manufacturing arrangements; (2) additions or modifications to product labeling; (3) the recall or discontinuation of our products; or (4) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Patient Protection and Affordable Care Act

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "PPACA"), was enacted, which includes measures that have or will significantly change the way healthcare is financed by both governmental and private insurers. Among the provisions of the PPACA of greatest importance to the pharmaceutical industry are the following:

- The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition for states to receive federal matching funds for the manufacturer's covered outpatient drugs furnished to Medicaid patients. Effective in 2010, the PPACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs and biologic agents to 23.1% of the average manufacturer prices ("AMP") and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The PPACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by expanding the population potentially eligible for Medicaid drug benefits. The CMS have proposed to expand Medicaid rebate liability to the territories of the United States as well. In addition, the PPACA provides for the public availability of retail survey prices and certain weighted average AMPs under the Medicaid program. The implementation of this requirement by the CMS may also provide for the public availability of pharmacy acquisition of cost data, which could negatively impact our sales.
- In order for a pharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. The PPACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly-eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs when used for the orphan indication. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.
- The PPACA imposes a requirement on manufacturers of branded drugs and biologic agents to provide a 50% discount off the negotiated price of branded drugs dispensed to Medicare Part D patients in the coverage gap (i.e., "donut hole").

- The PPACA imposes an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications.
- The PPACA requires pharmaceutical manufacturers to track certain financial arrangements with physicians and teaching hospitals, including any "transfer of value" made or distributed to such entities, as well as any investment interests held by physicians and their immediate family members. Manufacturers are required to track this information and were required to make their first reports in March 2014. The information reported is publicly available on a searchable website.
- As of 2010, a new Patient-Centered Outcomes Research Institute was established pursuant to the PPACA to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products.
- The PPACA created the Independent Payment Advisory Board, which has the authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription drugs. Under certain circumstances, these recommendations will become law unless Congress enacts legislation that will achieve the same or greater Medicare cost savings.
- The PPACA established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Funding has been allocated to support the mission of the Center for Medicare and Medicaid Innovation from 2011 to 2019.

Many of the details regarding the implementation of the PPACA are yet to be determined, and, at this time, the full effect of the PPACA on our business remains unclear. Further, there have been recent public announcements by members of the U.S. Congress, President Trump and his administration regarding their plans to repeal and replace the PPACA. For example, on December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act of 2017, which, among other things, eliminated the individual mandate requiring most Americans (other than those who qualify for a hardship exemption) to carry a minimum level of health coverage, effective January 1, 2019. We cannot predict the ultimate form or timing of any repeal or replacement of the PPACA or the effect such a repeal or replacement would have on our business.

Pediatric Exclusivity and Pediatric Use

Under the Best Pharmaceuticals for Children Act (the "BPCA"), certain drugs may obtain an additional six months of exclusivity if the sponsor submits information requested in writing by the FDA (a "Written Request") relating to the use of the active moiety of the drug in children. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. The FDA may not issue a Written Request for studies on unapproved or approved indications or where it determines that information relating to the use of a drug in a pediatric population, or part of the pediatric population, may not produce health benefits in that population. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

We have not received a Written Request for such pediatric studies, although we may ask the FDA to issue a Written Request for such studies in the future. To receive the six-month pediatric market exclusivity, we would need to receive a Written Request from the FDA, conduct the requested studies in accordance with a written agreement with the FDA or, if there is no written agreement, in accordance with commonly accepted scientific principles, and submit reports of the studies. A Written Request may include studies for indications that are not currently in the labeling if the FDA determines that such information will benefit the public health. The FDA will accept the reports upon its determination that the studies were conducted in accordance with, and are responsive to, the original Written Request or commonly accepted scientific principles, as appropriate, and that the reports comply with the FDA's filing requirements.

Under the Pediatric Research Equity Act of 2003 (the "PREA"), an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The PREA also authorizes the FDA to require holders of approved NDAs for marketed drugs to conduct pediatric studies under certain circumstances. With the enactment of the Food and Drug Administration Safety and Innovation Act (the "FDASIA"), in 2012, sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA and the FDA's internal review committee must then review the information submitted, consult with each other and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in the FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Employees

As of January 7, 2020, we had nine full-time employees in the United States. None of our employees are represented by a collective bargaining agreement. We believe that we have a good relationship with our employees.

Corporate Information

We were incorporated under the laws of the State of Delaware on August 4, 2009, as successor to BBM Holdings, Inc. (formerly known as Prime Resource, Inc., which was organized March 29, 2002 as a Utah corporation) pursuant to a reincorporation merger. On August 4, 2009, we reincorporated in Delaware as "Ohr Pharmaceutical, Inc." On July 12, 2019, we completed the Merger with NeuBase Corporation (formerly known as NeuBase Therapeutics, Inc.), a Delaware corporation, and, upon completion of the Merger, we changed our name to "NeuBase Therapeutics, Inc." Shares of our common stock commenced trading on the Nasdaq Capital Market under the ticker symbol "NBSE" as of market open on July 15, 2019.

Address

Our principal executive offices are located at 700 Technology Drive, Third Floor, Pittsburgh, PA 15219, and our telephone number is (646) 450-1790. Our website is located at www.neubasetherapeutics.com. Any information contained on, or that can be accessed through, our website is not incorporated by reference into, nor is it in any way part of this Form 10-K.

Available Information

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission (the "SEC"), and we have an Internet website address at www.neubasetherapeutics.com. We make available free of charge on our Internet website address our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Sections 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as well as our proxy statements as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. You may also obtain copies of such documents from the SEC's website at http://www.sec.gov.

ITEM 1A. RISK FACTORS

We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. Certain factors may have a material adverse effect on our business, prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this Annual Report on Form 10-K and our other public filings with the Securities and Exchange Commission (the "SEC"). Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

Risks Relating to the Company

We are a preclinical-stage company, have a very limited operating history, are not currently profitable, do not expect to become profitable in the near future and may never become profitable.

We are a preclinical-stage biotechnology company specializing in the discovery and development of a class of deoxy-ribonucleic acid and ribonucleic acid-targeted drugs called peptide nucleic acids, which will not change as a result of the merger between Ohr Pharmaceutical, Inc., a Delaware corporation ("Ohr"), and NeuBase Therapeutics, Inc., a Delaware corporation ("Legacy NeuBase"), in accordance with the terms of the Agreement and Plan of Merger Reorganization entered into on January 2, 2019 (the "Merger Agreement"). Since our incorporation, we have focused primarily on the development of our proprietary gamma Peptide-nucleic acid AnTisense OLigonucleotide ("PATrOL™") platform and preclinical-stage therapeutic candidates. Our platform technology and all of our therapeutic candidates are in the preclinical development stage, and we have not initiated clinical trials for any of our product candidates, nor have any products been approved for commercial sale and we have not generated any revenue. To date, we have not completed a clinical trial (including a pivotal clinical trial), obtained marketing approval for any product candidates, manufactured a commercial scale product or arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Drug development is also a highly uncertain undertaking and involves a substantial degree of risk.

As a result, we have no meaningful historical operations upon which to evaluate our business and prospects and have not yet demonstrated an ability to obtain marketing approval for any of our product candidates or successfully overcome the risks and uncertainties frequently encountered by companies in the pharmaceutical industry. We also have not generated any revenues from collaboration and licensing agreements or product sales to date and continue to incur research and development and other expenses. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' deficit and working capital, and our future success is subject to significant uncertainty.

For the foreseeable future, we expect to continue to incur losses, which will increase significantly from recent historical levels as we expand our drug development activities, seek regulatory approvals for our product candidates and begin to commercialize them if they are approved by the U.S. Food and Drug Administration (the "FDA"), the European Medicines Agency (the "EMA") or comparable foreign authorities. Even if we succeed in developing and commercializing one or more product candidates, we may never become profitable.

The approach we are taking to discover and develop nucleic acid therapeutics is novel and may never lead to marketable products.

We have concentrated our efforts and research and development activities on nucleic acid therapeutics and our synthetic chemistry drug discovery and development platform comprised of peptide nucleic acids with natural and engineered nucleotides. Our future success depends on the successful development and manufacturing of such therapeutics and the effectiveness of our platform. The scientific discoveries that form the basis for our efforts to discover and develop new drugs, including our discoveries about the relationships between oligonucleotide stereochemistry and pharmacology, are relatively new. The scientific evidence to support the feasibility of developing drugs based on these discoveries or peptide nucleic acids ("PNAs") in general is limited. Skepticism as to the feasibility of developing nucleic acid therapeutics and PNAs generally has been, and may continue to be, expressed in scientific literature. In addition, decisions by, and negative results of, other companies with respect to their oligonucleotide development efforts may increase skepticism in the marketplace regarding the potential for oligonucleotides and PNAs.

Relatively few nucleic acid therapeutic product candidates have been tested in humans, and a number of clinical trials for such therapeutics conducted by other companies have not been successful. Few nucleic acid therapeutics have received regulatory approval. The pharmacological properties ascribed to the investigational compounds we are testing in laboratory studies may not be positively demonstrated in clinical trials in patients, and they may interact with human biological systems in unforeseen, ineffective or harmful ways. If our nucleic acid product candidates prove to be ineffective, unsafe or commercially unviable, our entire platform and pipeline would have little, if any, value, which would substantially harm our business, financial condition, results of operations and prospects.

In addition, our approach, which focuses on using nucleic acid therapeutics for drug development, as opposed to multiple or other, more advanced proven technologies, may expose us to additional financial risks and make it more difficult to raise additional capital if we are not successful in developing a nucleic acid therapeutic that is timely and cost effective to manufacture and achieves proof of concept in animal models, desired tissue distribution, selectivity for the target, and/or regulatory approval. Because our programs are all in the research or preclinical stage, we have not yet been able to assess safety in humans, and there may be long-term effects from treatment with any product candidates that we develop using our platform that we cannot predict at this time. Any product candidates the Company may develop will act at the level of deoxyribonucleic acid ("DNA") or ribonucleic acid ("RNA"), and because animal DNA and RNA often differs from human DNA or RNA at the sequence level, in its regulation and degradation, secondary and tertiary structural conformations and ultimately in being translated into proteins with varying amino acid sequences conformations and functions, testing of our product candidates in animal models may not be predictive of the results we observe in human clinical trials of our product candidates for either safety or efficacy. Also, animal models may not exist for some of the diseases we choose to pursue in our programs. As a result of these factors, it is more difficult for us to predict the time and cost of product candidate development, and we cannot predict whether the application of our gene silencing technology, or any similar or competitive gene silencing technologies, will result in the identification, development and regulatory approval of any products. There can be no assurance that any development problems we experience in the future related to our gene silencing technology or any of our research programs will not cause significant delays or unanticipated costs, or that such development problems can be solved. Should we encounter development problems, including unfavorable preclinical or clinical trial results, the FDA and foreign regulatory authorities may refuse to approve our product candidates, or may require additional information, tests or trials, which could significantly delay product development and significantly increase our development costs. Moreover, even if we are able to provide the requested information or trials to the FDA, there would be no guarantee that the FDA would accept them or approve our product candidates. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or developing or qualifying and validating product release assays, other testing and manufacturing methods, and our equipment and facilities in a timely manner, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all. Any of these factors may prevent us from completing our preclinical studies or any clinical trials that we may initiate or from commercializing any product candidates we may develop on a timely or profitable basis, if at all.

We are highly dependent on the success of our initial product candidates targeting rare genetic diseases and our platform technology in general, and we cannot be certain that any of them will receive regulatory approval or be commercialized.

We have spent time, money and effort on the licensing and development of our core asset: our PATrOL™ platform. To date, we have not submitted an Investigational New Drug application ("IND") to the FDA, and no clinical trials have commenced for any of our product candidates. All of our product candidates will require additional development, including further preclinical studies and bioanalytic method development as well as clinical trials to evaluate their toxicology, carcinogenicity and pharmacokinetics, efficacy, and optimize their formulation, and regulatory clearances before they can be commercialized. Positive results obtained during early development do not necessarily mean later development will succeed or that regulatory clearances will be obtained. Our drug development efforts may not lead to commercial drugs, either because our product candidates or our PATrOL™ platform are not deemed safe and effective, because of competitive or market forces, intellectual property issues or because we have inadequate financial or other resources to advance our product candidates through the clinical development and approval processes. If any of our product candidates, or our PATrOL™ platform, fail to demonstrate safety or efficacy at any time or during any phase of development, we would experience potentially significant delays in, or be required to abandon, development of the product candidate.

We do not anticipate that any of our current product candidates will be eligible to receive regulatory approval from the FDA, the EMA or comparable foreign authorities and begin commercialization for a number of years, if ever. Even if we ultimately receive regulatory approval for any of these product candidates, we or our potential future partners, if any, may be unable to commercialize them successfully for a variety of reasons. These include, for example, the availability of alternative treatments, lack of cost-effectiveness, the cost of manufacturing the product on a commercial scale and competition with other drugs. The success of our product candidates and our PATrOL™ platform may also be limited by the prevalence and severity of any adverse side effects. If we fail to commercialize one or more of our current product candidates, we may be unable to generate sufficient revenues to attain or maintain profitability, and our financial condition may decline.

If development of our candidates does not produce favorable results, we and our collaborators, if any, may be unable to commercialize these products.

To receive regulatory approval for the commercialization of our use of the PATrOL™ platform, or any product candidates that we may develop, adequate and well-controlled clinical trials must be conducted to demonstrate safety and efficacy in humans to the satisfaction of the FDA, the EMA and comparable foreign authorities. In order to support marketing approval, these agencies typically require successful results in one or more Phase III clinical trials, which our current product candidates have not yet reached and may never reach. The development process is expensive, can take many years and has an uncertain outcome. Failure can occur at any stage of the process. We may experience numerous unforeseen events during, or as a result of, the development process that could delay or prevent commercialization of our current or future product candidates, including the following:

- preclinical studies conducted with product candidates for potential clinical development to evaluate their toxicology, carcinogenicity and pharmacokinetics and optimize their formulation, among other things, may produce unfavorable results;
- patient recruitment and enrollment in clinical trials may be slower than we anticipate;
- clinical trials may produce negative or inconclusive results;
- costs of development may be greater than we anticipate;
- the potential advantages of the PATrOL™-enabled drug candidates may not materialize and thus would confer no benefits to patients over other parties' products that may emerge;
- our product candidates or our PATrOL™ platform may cause undesirable side effects that delay or preclude regulatory approval or limit their commercial use or market acceptance, if approved;
- collaborators who may be responsible for the development of our product candidates may not devote sufficient resources to these clinical trials or other preclinical studies of these candidates or conduct them in a timely manner; or
- we may face delays in obtaining regulatory approvals to commence one or more clinical trials.

Additionally, because our technology potentially involves gene silencing via genome binding and/or editing across multiple cell and tissue types, we are subject to many of the challenges and risks that advanced therapies, such as gene therapies, face, including:

- regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future;
- improper modification of a gene sequence in a patient's genome could lead to lymphoma, leukemia or other cancers, or other aberrantly functioning cells; and
- the FDA recommends a follow-up observation period of 15 years or longer for all patients who receive treatment using gene therapies, and we may need to adopt and support such an observation period for our product candidates.

Success in early development does not mean that later development will be successful because, for example, product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy despite having progressed through initial clinical trials.

Furthermore, we have licensed or acquired virtually all of the intellectual property related to our product candidates from Carnegie Mellon University ("CMU"). Much of our preclinical studies and other analyses performed to date with respect to our product candidates have been conducted by their original owners or collaborators. Therefore, as a company, we have limited experience in conducting research on our platform technology and preclinical trials for our product candidates. Since our experience with our platform technology and product candidates is limited, we will need to train our existing personnel or hire additional personnel in order to successfully administer and manage our preclinical studies and clinical trials as anticipated, which may result in delays in completing such anticipated preclinical trials and clinical studies.

We currently do not have strategic collaborations in place for clinical development of our platform technology and any of our current product candidates. Therefore, in the future, we or any potential future collaborative partner will be responsible for establishing the targeted endpoints and goals for development of our product candidates. These targeted endpoints and goals may be inadequate to demonstrate the safety and efficacy levels required for regulatory approvals. Even if we believe data collected during the development of our product candidates are promising, such data may not be sufficient to support marketing approval by the FDA, the EMA or comparable foreign authorities. Further, data generated during development can be interpreted in different ways, and the FDA, the EMA or comparable foreign authorities may interpret such data in different ways than we or our collaborators. Our failure to adequately demonstrate the safety and efficacy of our platform technology and any of our product candidates would prevent our receipt of regulatory approval, and such failure would ultimately prevent the potential commercialization of these product candidates.

Since we do not currently possess the resources necessary to independently develop and commercialize our product candidates or any other product candidates that we may develop, we may seek to enter into collaborative agreements to assist in the development and potential future commercialization of some or all of these assets as a component of our strategic plan. Our discussions with potential collaborators, however, may not lead to the establishment of collaborations on acceptable terms, if at all, or it may take longer than expected to establish new collaborations, leading to development and potential commercialization delays, which would adversely affect our business, financial condition and results of operations.

We expect to continue to incur significant research and development expenses, which may make it difficult for us to attain profitability.

We expect to expend substantial funds in research and development, including preclinical studies and clinical trials for our platform technology and product candidates, and to manufacture and market any product candidates in the event they are approved for commercial sale. We will likely need additional funding to develop or acquire complementary companies, technologies and assets, as well as for working capital requirements and other operating and general corporate purposes. Moreover, an increase in our headcount would dramatically increase our costs in the near and long-term.

Such spending may not yield any commercially viable products. Due to our limited financial and managerial resources, we must focus on a limited number of research programs and product candidates and on specific indications. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Because the successful development of our product candidates is uncertain, we are unable to precisely estimate the actual funds we will require to develop and potentially commercialize them. In addition, we may not be able to generate sufficient revenue, even if we are able to commercialize any of our product candidates, to become profitable.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we will initially develop our lead product candidate for particular rare genetic diseases. As a result, we may forego or delay pursuit of opportunities in other types of diseases that may prove to have greater treatment potential. Likewise, we may forego or delay the pursuit of opportunities with other potential product candidates that may prove to have greater commercial potential.

Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the product candidate.

Given our lack of current cash flow, we will need to raise additional capital; however, it may be unavailable to us or, even if capital is obtained, may cause dilution or place significant restrictions on our ability to operate our business.

Since we will be unable to generate sufficient, if any, cash flow to fund our operations for the foreseeable future, we will need to seek additional equity or debt financing to provide the capital required to maintain or expand our operations.

There can be no assurance that we will be able to raise sufficient additional capital on acceptable terms or at all. If such additional financing is not available on satisfactory terms, or is not available in sufficient amounts, we may be required to delay, limit or eliminate the development of business opportunities, and our ability to achieve our business objectives, our competitiveness, and our business, financial condition and results of operations may be materially adversely affected. In addition, we may be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our inability to fund our business could lead to the loss of your investment.

Our future capital requirements will depend on many factors, including, but not limited to:

- the scope, rate of progress, results and cost of our preclinical studies, clinical trials and other related activities;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the timing of, and the costs involved in, obtaining regulatory approvals for any of our current or future product candidates;
- the number and characteristics of the product candidates it seeks to develop or commercialize;
- the cost of manufacturing clinical supplies, and establishing commercial supplies, of our product candidates;
- the cost of commercialization activities if any of our current or future product candidates are approved for sale, including marketing, sales and distribution costs;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing possible patent claims, including litigation costs and the outcome of any such litigation.

Any additional capital efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Moreover, if we raise additional capital by issuing equity securities, the percentage ownership of our existing stockholders may be reduced, and accordingly these stockholders may experience substantial dilution. We may also issue equity securities that provide for rights, preferences and privileges senior to those of our common stock. Given our need for cash and that equity issuances are the most common type of fundraising for similarly situated companies, the risk of dilution is particularly significant for our stockholders. Furthermore, the incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

The report of our independent registered public accounting firm expresses substantial doubt about our ability to continue as a going concern. Such "going concern" opinion could impair our ability to obtain financing.

Our independent registered public accounting firm, CohnReznick LLP, has indicated in their report on our financial statements for the fiscal year ended September 30, 2019 that conditions exist that raise substantial doubt about our ability to continue as a going concern due to our recurring losses from operations. A "going concern" opinion could impair our ability to finance our operations through the sale of equity, incurring debt, or other financing alternatives. Our ability to continue as a going concern will depend upon the availability and terms of future funding. If we are unable to achieve this goal, our business would be jeopardized and we may not be able to continue. If we ceased operations, it is likely that all of our investors would lose their investment.

Our efforts to discover product candidates beyond our current product candidates may not succeed, and any product candidates we recommend for clinical development may not actually begin clinical trials.

We intend to use our technology, including our licensed technology, knowledge and expertise, to develop novel drug candidates to address some of the world's most devastating and costly central nervous system, muscular, and other disorders, including orphan genetic and oncology indications. We intend to expand our existing pipeline of core assets by advancing drug candidate compounds from discovery programs into clinical development. However, the process of researching and discovering drug candidate compounds is expensive, time-consuming and unpredictable. Data from our current preclinical programs may not support the clinical development of our lead compounds or other compounds from these programs, and we may not identify any additional drug compounds suitable for recommendation for clinical development. Moreover, any drug compounds we recommend for clinical development may not demonstrate, through preclinical studies, indications of safety and potential efficacy that would support advancement into clinical trials. Such findings would potentially impede our ability to maintain or expand our clinical development pipeline. Our ability to identify new drug compounds and advance them into clinical development also depends upon our ability to fund our research and development operations, and we cannot be certain that additional funding will be available on acceptable terms, or at all.

We are significantly dependent on the success of our PATrOL™ platform and our product candidates based on this platform. A failure of any product candidate based on this platform in clinical development would adversely affect our business and may require us to discontinue development of other product candidates based on the same therapeutic approach.

We have invested, and we expect to continue to invest, significant efforts and financial resources in the development of product candidates based on our PATrOL™ platform. Our ability to generate meaningful revenue, which may not occur for the foreseeable future, if ever, will depend heavily on the successful development, regulatory approval and commercialization of one or more of these product candidates using our PATrOL™ platform. We will not be able to develop new product candidates if it is found that the PATrOL™ platform does not work or creates product candidates that are not safe for use in humans. Since all of our product candidates in our current pipeline are based on our PATrOL™ platform, if any product candidate fails in development as a result of an underlying problem with our PATrOL™ platform, then we may be required to discontinue development of all product candidates that are based on our therapeutic approach. If we were required to discontinue the development of such product candidates based on the PATrOL™ platform, or if any of them were to fail to receive regulatory approval or achieve sufficient market acceptance, we could be prevented from or significantly delayed in achieving profitability. We can provide no assurance that we would be successful at developing other product candidates based on an alternative therapeutic approach from our PATrOL™ platform.

The pharmaceutical market and biotechnology industry are intensely competitive and involve a high degree of risk. If we are unable to compete effectively with existing drugs, new treatment methods and new technologies, we may be unable to commercialize successfully any drug candidates that we develop.

The pharmaceutical market and biotechnology industry are intensely competitive and rapidly changing. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations, both in the U.S. and worldwide, are pursuing the development of novel drugs for the same diseases that we are targeting or expect to target. Many of our competitors have, either alone or with strategic partners:

- much greater financial, research, technical and human resources than we have at every stage of the discovery, development, manufacture and commercialization of products and product candidates;
- more extensive experience in designing and conducting preclinical studies and clinical trials, obtaining regulatory approvals, and in manufacturing, marketing and selling pharmaceutical products and product candidates;
- product candidates that are based on previously tested or accepted technologies;
- products and product candidates that have been approved or are in late stages of development; and
- collaborative arrangements in our target markets with leading companies and research institutions.

We will face intense competition from drugs that have already been approved and accepted by the medical community for the treatment of the conditions for which we may develop drug candidates. We also expect to face competition from new drugs that enter the market. We believe there are a significant number of drugs currently under development that may become commercially available in the future, for the treatment of conditions for which we may try to develop drugs. These drugs may be more effective, safer, less expensive, introduced to market earlier, or marketed and sold more effectively or on a more cost-effective basis, than any product candidates we develop. It is possible that the potential advantages of PATrOL™-derived therapeutic candidates (including, among other potential advantages, the ability to systemically deliver drugs and get broad tissue distribution and penetration across the blood-brain barrier, minimal to no innate or adaptive immune responses after single dose or multiple-dose administration, preferential selectivity to mutant targets, and dose schedules to address the disease appropriately or that is viable in the marketplace) do not materialize.

Our competitors may develop or commercialize products with significant advantages over any product candidates we are able to develop and commercialize based on many different factors, including:

- the safety and effectiveness of our product candidates relative to alternative therapies, if any;
- the ease with which our product candidates can be administered and the extent to which patients accept relatively new routes of administration;
- the timing and scope of regulatory approvals for these product candidates;
- the availability and cost of manufacturing, marketing and sales capabilities;
- price;
- reimbursement coverage from governments and other third-party payors; and
- patent position and intellectual property protection.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are viewed as safer, more effective, more convenient or less expensive than any products that we may develop. Our competitors may also obtain FDA or other regulatory approval for their competing products more rapidly than we may obtain approval for any of our product candidates, which could result in our competitors establishing a strong market position before we are able to enter the market. Further, we expect that we will also compete with others when recruiting clinical trial sites and subjects for our clinical trials and when recruiting and retaining qualified scientific and management personnel.

While there are currently no approved treatments available to slow the progression of Huntington's Disease ("HD"), publicly available information shows that a number of companies are pursuing product candidates related to HD. These include an investigational drug in Phase III clinical development, several ongoing clinical and preclinical programs targeting the underlying disease in HD and the development of drugs focused on treating the symptoms associated with HD. Similarly, both companies and non-commercial sponsors are investigating agents and conducting research, clinical trials and controlled studies regarding different treatments for Myotonic Dystrophy. The success of any of these competitors could reduce or eliminate our commercial opportunity.

Any collaboration arrangement that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our current and potential future product candidates.

We may seek collaboration arrangements with pharmaceutical companies for the development or commercialization of our current and potential future product candidates. To the extent that we decide to enter into collaboration agreements, we will face significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, execute and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we choose to enter into such arrangements, and the terms of the arrangements may not be favorable to us. If and when we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. As such, our inability to control our collaborators, and the potentially adverse results of our collaborators, may materially and adversely affect our product candidates and, more generally, our PATrOL™ platform, and we may not be able to conduct our program in the manner or on the time schedule it currently contemplates, which could negatively impact our business.

If our potential future collaborations do not result in the successful discovery, development and commercialization of products or if one of our collaborators terminates our agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our platform technology and product candidates could be delayed and we may need additional resources to develop product candidates and our technology.

Finally, disagreements between parties to a collaboration arrangement can lead to delays in developing or commercializing the applicable product candidate and can be difficult to resolve in a mutually beneficial manner. In some cases, collaborations with biopharmaceutical companies and other third parties are terminated or allowed to expire by the other party. Any such termination or expiration could adversely affect our business, financial condition and results of operations.

We, or any future collaborators, may not be able to obtain orphan drug designation or orphan drug exclusivity for our product candidates.

Regulatory authorities in some jurisdictions, including the U.S. and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the U.S. In the U.S. and Europe, obtaining orphan drug approval may allow us to obtain financial incentives, such as an extended period of exclusivity during which only we are allowed to market the orphan drug for the orphan indications that we are developing. While we may seek orphan drug designation from the FDA for any of our product candidates, we, or any future collaborators, may not be granted orphan drug designations for our product candidates in the U.S. or in other jurisdictions.

Even if we or any future collaborators obtain orphan drug designation for a product candidate, we or such collaborators may not be able to obtain orphan drug exclusivity for that product candidate. Generally, a product with orphan drug designation only becomes entitled to orphan drug exclusivity if it receives the first marketing approval for the indication for which it has such designation, in which case the FDA or the EMA will be precluded from approving another marketing application for the same drug for that indication for the applicable exclusivity period. The applicable exclusivity period is seven years in the U.S. and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we or any future collaborators obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because FDA has taken the position that, under certain circumstances, another drug with the same active chemical and pharmacological characteristics, or moiety, can be approved for the same condition. Specifically, the FDA's regulations provide that it can approve another drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates.

The process of manufacturing our product candidates is complex, highly regulated, and subject to several risks. For example, the process of manufacturing our product candidates is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing processes for any of our product candidates could result in reduced production yields, product defects, and other supply disruptions. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. In addition, the manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors. For instance, our therapeutic molecules are complex and comprised of both peptides and nucleic acids, and it may be difficult or impossible to find Good Laboratory Practice- ("GLP") and Current Good Manufacturing Practice- ("cGMP") grade manufacturers, manufacturing may be cost prohibitive, we or our third-party manufacturers may not be able to manufacture product candidates in a timely manner, or manufacturing may not be available to fulfill regulatory requirements. In addition, we or our third-party manufacturers may not be able to manufacture our product candidates in a timely manner.

In addition, any adverse developments affecting manufacturing operations for our product candidates may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls, or other interruptions in the supply of our product candidates. We also may need to take inventory write-offs and incur other charges and expenses for product candidates that fail to meet specifications, undertake costly remediation efforts or seek costlier manufacturing alternatives.

We rely, and will continue to rely, predominantly, on third parties to manufacture our preclinical and clinical drug supplies and our business, financial condition and results of operations could be harmed if those third parties fail to provide us with sufficient quantities of drug product, or fail to do so at acceptable quality levels, prices, or timelines.

We have the capability internally to manufacture small quantities of our drugs for preclinical studies. However, we do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture our clinical drug supplies for use in our clinical trials, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our product candidates, and there may be a need to identify alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and, if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Any significant delay or discontinuity in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates, which could harm our business, financial condition and results of operations.

If we are unable to develop our own commercial organization or enter into agreements with third parties to sell and market our product candidates, we may be unable to generate significant revenues.

We do not have a sales and marketing organization, and we have no experience as a company in the sales, marketing and distribution of pharmaceutical products. If any of our product candidates are approved for commercialization, we may be required to develop our own sales, marketing and distribution capabilities, or make arrangements with a third party to perform sales and marketing services. Developing a sales force for any resulting product or any product resulting from any of our other product candidates is expensive and time consuming and could delay any product launch. We may be unable to establish and manage an effective sales force in a timely or cost-effective manner, if at all, and any sales force we do establish may not be capable of generating sufficient demand for our product candidates. To the extent that we enter into arrangements with collaborators or other third parties to perform sales and marketing services, our product revenues are likely to be lower than if we marketed and sold our product candidates independently. If we are unable to establish adequate sales and marketing capabilities, independently or with others, we may not be able to generate significant revenues and may not become profitable.

The commercial success of our product candidates depends upon their market acceptance among physicians, patients, healthcare payors and the medical community.

Even if our product candidates obtain regulatory approval, our products, if any, may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the effectiveness of our approved product candidates as compared to currently available products;
- patient willingness to adopt our approved product candidates in place of current therapies;
- our ability to provide acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- restrictions on use in combination with other products;
- availability of alternative treatments;
- pricing and cost-effectiveness assuming either competitive or potential premium pricing requirements, based on the profile of our product candidates and target markets;
- effectiveness of our or our partners' sales and marketing strategy;
- our ability to obtain sufficient third-party coverage or reimbursement; and
- potential product liability claims.

In addition, the potential market opportunity for our product candidates is difficult to precisely estimate. Our estimates of the potential market opportunity for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research reports and other surveys. Independent sources have not verified all of our assumptions. If any of these assumptions proves to be inaccurate, then the actual market for our product candidates could be smaller than our estimates of our potential market opportunity. If the actual market for our product candidates is smaller than we expect, our product revenue may be limited, it may be harder than expected to raise funds and it may be more difficult for us to achieve or maintain profitability. If we fail to achieve market acceptance of our product candidates in the U.S. and abroad, our revenue will be limited and it will be more difficult to achieve profitability.

If we fail to obtain and sustain an adequate level of reimbursement for our potential products by third-party payors, potential future sales would be materially adversely affected.

There will be no viable commercial market for our product candidates, if approved, without reimbursement from third-party payors. Reimbursement policies may be affected by future healthcare reform measures. We cannot be certain that reimbursement will be available for our current product candidates or any other product candidate we may develop. Additionally, even if there is a viable commercial market, if the level of reimbursement is below our expectations, our anticipated revenue and gross margins will be adversely affected.

Third-party payors, such as government or private healthcare insurers, carefully review and increasingly question and challenge the coverage of and the prices charged for drugs. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan and other factors. Reimbursement rates may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. There is a current trend in the U.S. healthcare industry toward cost containment.

Large public and private payors, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payors, including Medicare, may question the coverage of, and challenge the prices charged for, medical products and services, and many third-party payors limit coverage of or reimbursement for newly approved healthcare products. In particular, third-party payors may limit the covered indications. Cost-control initiatives could decrease the price we might establish for products, which could result in product revenues being lower than anticipated. We believe our drugs will be priced significantly higher than existing generic drugs and consistent with current branded drugs. If we are unable to show a significant benefit relative to existing generic drugs, Medicare, Medicaid and private payors may not be willing to provide reimbursement for our drugs, which would significantly reduce the likelihood of our products gaining market acceptance.

We expect that private insurers will consider the efficacy, cost-effectiveness, safety and tolerability of our product candidates in determining whether to approve reimbursement for such product candidates and at what level. Obtaining these approvals can be a time consuming and expensive process. Our business, financial condition and results of operations would be materially adversely affected if we do not receive approval for reimbursement of our product candidates from private insurers on a timely or satisfactory basis. Limitations on coverage could also be imposed at the local Medicare carrier level or by fiscal intermediaries. Medicare Part B, which covers medical insurance to Medicare patients as discussed below, does not require participating insurance plans to cover all drugs that have been approved by the FDA. Our business, financial condition and results of operations could be materially adversely affected if Part B medical insurance were to limit access to, or deny or limit reimbursement of, our product candidates.

Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis. In many countries, the product candidate cannot be commercially launched until reimbursement is approved. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. The negotiation process in some countries can exceed 12 months. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies.

If the prices for our product candidates are reduced or if governmental and other third-party payors do not provide adequate coverage and reimbursement of our drugs, our future revenue, cash flows and prospects for profitability will suffer.

We are exposed to product liability, non-clinical and clinical liability risks which could place a substantial financial burden upon us, should lawsuits be filed against us.

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical formulations and products. In addition, the use in our anticipated clinical trials of pharmaceutical products and the subsequent sale of product candidates by us, if approved, or our potential collaborators may cause us to bear a portion of or all product liability risks. A successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

Because we do not currently have any clinical trials ongoing, we do not currently carry product liability insurance. We anticipate obtaining such insurance upon initiation of our clinical development activities; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could adversely affect our results of operations and business if judgments therewith exceed our insurance coverage.

If we fail to retain current members of our management, or to attract and keep additional key personnel, we may be unable to successfully develop or commercialize our product candidates.

Our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. As of January 7, 2020, we had nine full-time employees. We will rely primarily on outsourcing research, development and clinical trial activities, and manufacturing operations, as well as other functions critical to our business. We believe this approach enhances our ability to focus on our core product opportunities, allocate resources efficiently to different projects and allocate internal resources more effectively. We have filled several key open positions and are currently recruiting for a few remaining positions. However, competition for qualified personnel is intense. We may not be successful in attracting qualified personnel to fulfill our current or future needs. In the event we are unable to fill critical open employment positions, we may need to delay our operational activities and goals, including the development of our product candidates, and may have difficulty in meeting our obligations as a public company. We do not maintain "key person" insurance on any of our employees.

In addition, competitors and others are likely in the future to attempt to recruit our employees. The loss of the services of any of our key personnel, the inability to attract or retain highly qualified personnel in the future or delays in hiring such personnel, particularly senior management and other technical personnel, could materially and adversely affect our business, financial condition and results of operations. In addition, the replacement of key personnel likely would involve significant time and costs, and may significantly delay or prevent the achievement of our business objectives.

From time to time, our management seeks the advice and guidance of certain scientific advisors and consultants regarding clinical and regulatory development programs and other customary matters. These scientific advisors and consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our scientific advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with us.

We will need to increase the size of our organization and may not successfully manage our growth.

We are a preclinical-stage pharmaceutical company with a small number of employees, and our management systems currently in place are not likely to be adequate to support our future growth plans. Our ability to grow and to manage our growth effectively will require us to hire, train, retain, manage and motivate additional employees and to implement and improve our operational, financial and management systems. These demands also may require the hiring of additional senior management personnel or the development of additional expertise by our senior management personnel. Hiring a significant number of additional employees, particularly those at the management level, would increase our expenses significantly. Moreover, if we fail to expand and enhance our operational, financial and management systems in conjunction with our potential future growth, such failure could have a material adverse effect on our business, financial condition and results of operations.

Because our Chief Executive Officer is involved with several unaffiliated privately-held companies, he may experience conflicts of interest and competing demands for his time and attention.

Dietrich Stephan, Ph.D., our Chief Executive Officer, is a member of the governing bodies of several unaffiliated privately-held companies, as well as a general partner of Cyto Ventures. Although Dr. Stephan expects to devote substantially all of his time to us, he expects to continue in each of these positions for the foreseeable future. Conflicts of interest could arise with respect to business opportunities that could be advantageous to third party organizations affiliated with Dr. Stephan, on the one hand, and us, on the other hand.

The majority of our current management lacks public company experience, which could put us at greater risk of incurring fines or regulatory actions for failure to comply with federal securities laws and could put us at a competitive disadvantage and require our management to devote additional time and resources to ensure compliance with applicable corporate governance requirements.

The majority of our current executive management do not have experience in managing and operating a public company, which could have an adverse effect on our ability to quickly respond to problems or adequately address issues and matters applicable to public companies. Any failure to comply with federal securities laws, rules or regulations could subject us to fines or regulatory actions, which may materially adversely affect our business, financial condition and results of operations. Further, since certain of our current executive officers do not have experience managing and operating a public company, we may need to dedicate additional time and resources to comply with legally mandated corporate governance policies relative to our competitors whose management teams have more public company experience.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our drug development and preclinical and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of drug development or clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs and the development of our product candidates could be delayed.

Our employees, consultants, third-party vendors and collaborators may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee, consultant, third-party vendor or collaborator fraud or other misconduct. Misconduct by our employees, consultants, third-party vendors or collaborators could include, among other things, intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commissions, customer incentive programs and other business arrangements. Employee, consultant, vendor or collaborator misconduct also could involve the improper use of information obtained in the course of preclinical or clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter such misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material adverse effect on our business, financial condition and results of operations, and result in the imposition of significant fines or other sanctions against us.

Business disruptions such as natural disasters could seriously harm our future revenues and financial condition and increase our costs and expenses.

We and our suppliers may experience a disruption in our and their business as a result of natural disasters. A significant natural disaster, such as an earthquake, hurricane, flood or fire, could severely damage or destroy our headquarters or facilities or the facilities of our manufacturers or suppliers, which could have a material and adverse effect on our business, financial condition and results of operations. In addition, terrorist acts or acts of war targeted at the U.S., and specifically the Pittsburgh, Pennsylvania and greater New York, New York regions, could cause damage or disruption to us, our employees, facilities, partners and suppliers, which could have a material adverse effect on our business, financial condition and results of operations.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Additional potential transactions that we may consider include a variety of different business arrangements, including acquisitions of companies, asset purchases and out-licensing or in-licensing of products, product candidates or technologies. Any such transaction may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our business, financial condition and results of operations. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for any of these transactions;
- higher-than-expected transaction and integration costs;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses or product lines with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses or product lines due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks, and could have a material adverse effect on our business, financial condition and results of operations.

The estimates and judgments we make, or the assumptions on which we rely, in preparing our financial statements could prove inaccurate.

Our financial statements have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges accrued by us and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. We cannot assure, however, that our estimates, or the assumptions underlying them, will not change over time or otherwise prove inaccurate. For example, our estimates as they relate to anticipated timelines and milestones for our preclinical development or clinical trials may prove to be inaccurate. If this is the case, we may be required to restate our financial statements, which could, in turn, subject us to securities class action litigation or regulatory investigation or action. Defending against such potential litigation or regulatory action relating to a restatement of our financial statements would be expensive and would require significant attention and resources of our management. Moreover, our insurance to cover our obligations with respect to the ultimate resolution of any such litigation or regulatory action may be inadequate. As a result of these factors, any such potential litigation or regulatory action could have a material adverse effect on our financial results or harm our business.

We may be unable to sell or otherwise monetize, the assets and technologies of the Company as conducted prior to the completion of the Merger, in which case we may be required to take write-downs, write-offs and impairment or other charges associated with the carrying values of such assets. Any such charges could negatively affect our business, assets, liabilities, prospects, outlook, financial condition and results of operations.

Previously, Ohr acquired the SKS Ocular 1 LLC sustained release technology, which was designed to develop best in class drug formulations for ocular disease (the "SKS Assets") and the exclusive rights to an animal model for dry macular degeneration and rights to produce and use carboxyethylpyrrole ("CEP") for research, clinical and commercial applications (the "CEP Assets"). In September 2019, we terminated the licenses for the SKS Assets and the CEP Assets, as there would be substantial costs associated with continuing to maintain such assets and attempts to monetize such assets would be a distraction to our management and other employees and an inefficient use of their time. Our management and board of directors continue to evaluate whether to further pursue monetizing the remaining assets associated with our pre-Merger activities, including selling, discontinuing or adjusting such assets. There can be no assurance, however, that we will be successful at such efforts or sell or otherwise monetize such assets on acceptable terms, if at all. We may be required to take write-offs or write-downs, and impairment or other charges associated with classifying such remaining assets as held-for-sale and recording the carrying values of such assets at fair market value. As a result, we may be forced to write-down or write-off such assets, in some cases completely, or incur impairment or other charges that could negatively affect our business, assets, liabilities, prospects, outlook, financial condition and results of operations.

We have determined that our accounting treatment and valuation of consideration pertaining to the license of our PATrOL™ technology should be modified. This change in accounting treatment has required us to adjust our financial statements and will likely result in adjustments of our previously reported financial statements. If we identify errors in our financial reporting in the future, we may be required to restate previously reported financial statements and any such restatement may subject us to regulatory penalties and could cause investors to lose confidence in the accuracy and completeness of our financial statements, which could cause the price of our common stock to decline.

In connection with the preparation of our financial statements, our management and the audit committee of our board of directors determined that our accounting treatment and valuations pertaining to the PATrOL™ technology license should be modified. This change in accounting treatment resulted in an increase in total operating expenses of approximately $0.9 million on our Consolidated Statements of Operations and a decrease in intangible assets of approximately $1.5 million on our Consolidated Balance Sheet. In connection with the valuation adjustments to the PATrOL™ technology license, we also determined that valuations pertaining to certain share-based awards should also be adjusted. This change in valuation to share-based awards resulted in a decrease in total operating expenses of approximately $0.3 million on our Consolidated Statements of Operations. This change in accounting treatment will likely lead to adjustments of our previously reported financial statements. If we are required to restate any of our financial statements in the future, we may be subject to regulatory penalties and investors could lose confidence in the accuracy and completeness of our financial statements, which could cause our share price to decline.

Risks Related to Our Intellectual Property

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

Because several of our programs currently require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to maintain and exploit these proprietary rights. In addition, we may need to acquire or in-license additional intellectual property in the future. We may be unable to acquire or in-license any compositions, methods of use, processes or other intellectual property rights from third parties that we identify as necessary for our product candidates. We face competition with regard to acquiring and in-licensing third-party intellectual property rights, including from a number of more established companies. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license intellectual property rights to us. We also may be unable to acquire or in-license third-party intellectual property rights on terms that would allow it to make an appropriate return on our investment, and we may not be able to market products or perform research and development or other activities covered by these patents.

We may enter into collaboration agreements with U.S. and foreign academic institutions to accelerate development of our current or future preclinical product candidates. Typically, these agreements include an option for the company to negotiate a license to the institution's intellectual property rights resulting from the collaboration. Even with such an option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to license rights from a collaborating institution, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our desired program.

If we are unable to successfully obtain required third-party intellectual property rights or maintain our existing intellectual property rights, we may need to abandon development of the related program and our business, financial condition and results of operations could be materially and adversely affected.

If we fail to comply with our obligations in the agreements under which we in-license intellectual property and other rights from third parties or otherwise experiences disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.

Our license agreement with CMU (the "CMU License Agreement"), as the licensor (the "Licensor"), is important to our business, and we expect to enter into additional license agreements in the future. The CMU License Agreement imposes, and we expect that future license agreements will impose, various royalties, sublicensing fees and other obligations on us. If we fail to comply with our obligations under these agreements, or if we file for bankruptcy, we may be required to make certain payments to the Licensor, we may lose the exclusivity of our license, or the Licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. Additionally, the royalties and other payments associated with these licenses could materially and adversely affect our business, financial condition and results of operations.

Pursuant to the terms of the CMU License Agreement, the Licensor has the right to terminate the CMU License Agreement with respect to the program licensed under certain circumstances, including, but not limited to: (i) if we do not pay amounts when due and within the applicable cure periods or (ii) if we file or have filed against us a petition in bankruptcy or makes an assignment for the benefit of creditors. In the event the CMU License Agreement is terminated by the Licensor, all licenses (or, in the determination of the Licensor, the exclusivity of such licenses) granted to us by the Licensor will terminate immediately.

In some cases, patent prosecution of our licensed technology may be controlled solely by the licensor. If our licensor fails to obtain and maintain patent or other protection for the proprietary intellectual property we in-license, then we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, we may control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise regarding intellectual property subject to a licensing agreement, including, but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

If disputes over intellectual property and other rights that we have in-licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. If we fail to comply with any such obligations to our licensor, such licensor may terminate their licenses to us, in which case we would not be able to market products covered by these licenses. The loss of our licenses would have a material adverse effect on our business, financial condition and results of operations.

We may be required to pay royalties and sublicensing fees pursuant to the CMU License Agreement, which could adversely affect the overall profitability for us of any product candidates that we may seek to commercialize.

Under the terms of the CMU License Agreement, we will be required to pay royalties on future worldwide net product sales and a percentage of sublicensing fees that we may earn. These royalty payments and sublicensing fees could adversely affect the overall profitability for us of any product candidates that we may seek to commercialize.

We may not be able to protect our proprietary or licensed technology in the marketplace.

We depend on our ability to protect our proprietary or licensed technology. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our success depends in large part on our ability and any licensor's or licensee's ability to obtain and maintain patent protection in the U.S. and other countries with respect to our proprietary or licensed technology and product candidates. We currently in-license some of our intellectual property rights to develop our product candidates and may in-license additional intellectual property rights in the future. We cannot be certain that patent enforcement activities by our current or future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. We also cannot be certain that our current or future licensors will allocate sufficient resources or prioritize their or our enforcement of such patents. Even if we are not a party to these legal actions, an adverse outcome could prevent us from continuing to license intellectual property that we may need to operate our business, which would have a material adverse effect on our business, financial condition and results of operations.

We believe we will be able to obtain, through prosecution of patent applications covering our owned technology and technology licensed from others, adequate patent protection for our proprietary drug technology, including those related to our in-licensed intellectual property. If we are compelled to spend significant time and money protecting or enforcing our licensed patents and future patents we may own, designing around patents held by others or licensing or acquiring, potentially for large fees, patents or other proprietary rights held by others, our business, financial condition and results of operations may be materially and adversely affected. If we are unable to effectively protect the intellectual property that we own or in-license, other companies may be able to offer the same or similar products for sale, which could materially adversely affect our business, financial condition and results of operations. The patents of others from whom we may license technology, and any future patents we may own, may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing the same or similar products or limit the length of term of patent protection that we may have for our products.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection for licensed patents, licensed pending patent applications and potential future patent applications and patents could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or patent applications will be due to be paid to the U.S. Patent and Trademark Office ("USPTO") and various governmental patent agencies outside of the U.S. in several stages over the lifetime of the applicable patent and/or patent application. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If this occurs with respect to our in-licensed patents or patent applications we may file in the future, our competitors might be able to use our technologies, which would have a material adverse effect on our business, financial condition and results of operations.

The patent positions of pharmaceutical products are often complex and uncertain. The breadth of claims allowed in pharmaceutical patents in the U.S. and many jurisdictions outside of the U.S. is not consistent. For example, in many jurisdictions, the support standards for pharmaceutical patents are becoming increasingly strict. Some countries prohibit method of treatment claims in patents. Changes in either the patent laws or interpretations of patent laws in the U.S. and other countries may diminish the value of our licensed or owned intellectual property or create uncertainty. In addition, publication of information related to our current product candidates and potential products may prevent us from obtaining or enforcing patents relating to these product candidates and potential products, including without limitation composition-of-matter patents, which are generally believed to offer the strongest patent protection.

Patents that we currently licenses and patents that we may own or license in the future do not necessarily ensure the protection of our licensed or owned intellectual property for a number of reasons, including, without limitation, the following:

- the patents may not be broad or strong enough to prevent competition from other products that are identical or similar to our product candidates;
- there can be no assurance that the term of a patent can be extended under the provisions of patent term extensions afforded by U.S. law or similar provisions in foreign countries, where available;
- the issued patents and patents that we may obtain or license in the future may not prevent generic entry into the market for our product candidates;
- we, or third parties from whom we in-license or may license patents, may be required to disclaim part of the term of one or more patents;
- there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim;
- there may be prior art of which we are aware, which we do not believe affects the validity or enforceability of a patent claim, but which, nonetheless, ultimately may be found to affect the validity or enforceability of a patent claim;
- there may be other patents issued to others that will affect our freedom to operate;
- if the patents are challenged, a court could determine that they are invalid or unenforceable;
- there might be a significant change in the law that governs patentability, validity and infringement of our licensed patents or any future patents we may own that adversely affects the scope of our patent rights;
- a court could determine that a competitor's technology or product does not infringe our licensed patents or any future patents we may own; and
- the patents could irretrievably lapse due to failure to pay fees or otherwise comply with regulations or could be subject to compulsory licensing.

If we encounter delays in our development or clinical trials, the period of time during which we could market our potential products under patent protection would be reduced.

Our competitors may be able to circumvent our licensed patents or future patents we may own by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may seek to market generic versions of any approved products by submitting abbreviated new drug applications to the FDA in which our competitors claim that our licensed patents or any future patents we may own are invalid, unenforceable or not infringed. Alternatively, our competitors may seek approval to market their own products similar to or otherwise competitive with our product candidates. In these circumstances, we may need to defend or assert our licensed patents or any future patents we may own, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our licensed patents or any future patents we may own invalid or unenforceable. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Even if we own or in-license valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

The issuance of a patent is not conclusive as to its inventorship, scope, ownership, priority, validity or enforceability. In this regard, third parties may challenge our licensed patents or any future patents we may own in the courts or patent offices in the U.S. and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and potential products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized.

We may infringe the intellectual property rights of others, which may prevent or delay our drug development efforts and prevent us from commercializing or increase the costs of commercializing our product candidates.

Our commercial success depends significantly on our ability to operate without infringing the patents and other intellectual property rights of third parties. For example, there could be issued patents of which we are not aware that our current or potential future product candidates infringe. There also could be patents that we believe we do not infringe, but that we may ultimately be found to infringe. We have licensed intellectual property from CMU under the CMU License Agreement, and prior generation intellectual property was licensed to other entities. Such intellectual property, in conjunction with further developed technologies for gene editing therapies using such intellectual property, may overlap with our own intellectual property.

Furthermore, because the nucleic acid therapeutics intellectual property landscape is still evolving and our product candidates have not been through clinical trials or commercialized, it is difficult to conclusively assess our freedom to operate without infringing third party rights. There are numerous companies that have pending patent applications and issued patents directed to certain aspects of nucleic acid therapeutics. We are aware of third party competitors in the oligonucleotide therapeutics space, whose patent filings and/or issued patents may include claims directed to targets and/or products related to some of our programs. It is possible that at the time that we commercialize our products these third-party patent portfolios may include issued patent claims that cover our product candidates or critical features of their production or use. Our competitive position may suffer if patents issued to third parties or other third party intellectual property rights cover, or may be alleged to cover, our product candidates or elements thereof, or methods of manufacture or use relevant to our development plans. In such cases, we may not be in a position to develop or commercialize product candidates unless we successfully pursue litigation to nullify or invalidate the third party intellectual property right concerned or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms.

Moreover, patent applications are in some cases maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications were filed. Because patents can take many years to issue, there may be currently pending applications of which we are unaware that may later result in issued patents that our product candidates or potential products infringe. For example, pending applications may exist that claim or can be amended to claim subject matter that our product candidates or potential products infringe. Competitors may file continuing patent applications claiming priority to already issued patents in the form of continuation, divisional, or continuation-in-part applications, in order to maintain the pendency of a patent family and attempt to cover our product candidates.

Third parties may assert that we are employing their proprietary technology without authorization and may sue us for patent or other intellectual property infringement. These lawsuits are costly and could adversely affect our business, financial condition and results of operations and divert the attention of managerial and scientific personnel. If we are sued for patent infringement, we would need to demonstrate that our product candidates, potential products or methods either do not infringe the claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the U.S., proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. If a court holds that any third-party patents are valid, enforceable and cover our products or their use, the holders of any of these patents may be able to block our ability to commercialize our products unless it acquires or obtains a license under the applicable patents or until the patents expire.

We may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost or on reasonable terms. Any inability to secure licenses or alternative technology could result in delays in the introduction of our product candidates or lead to prohibition of the manufacture or sale of products by us. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product candidate. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially and adversely affect our business, financial condition and results of operations. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar material and adverse effect on our business, financial condition and results of operations. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Our product candidates may also require specific formulations to work effectively and efficiently. These formulations may be covered by intellectual property rights held by others. We may develop products containing our compounds and pre-existing pharmaceutical compounds. These pharmaceutical compounds may be covered by intellectual property rights held by others. We may be required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our product candidates. These diagnostic test or tests may be covered by intellectual property rights held by others. We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business operations.

We, or our licensors, may not be able to detect infringement against our owned or in-licensed patents, as the case may be, which may be especially difficult for manufacturing processes or formulation patents. Even if we or our licensors detect infringement by a third party of our owned or in-licensed patents, we or our licensors, as the case may be, may choose not to pursue litigation against or settlement with the third party. If we, or our licensors, later sue such third party for patent infringement, the third party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us or our licensors to enforce our owned or in-licensed patents, as the case may be, against such third party.

Any claims or lawsuits relating to infringement of intellectual property rights brought by or against us will be costly and time consuming and may adversely affect our business, financial condition and results of operations.

We may be required to initiate litigation to enforce or defend our licensed and owned intellectual property. Lawsuits to protect our intellectual property rights can be very time consuming and costly. There is a substantial amount of litigation involving patent and other intellectual property rights in the pharmaceutical industry generally. Such litigation or proceedings could substantially increase our operating expenses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are resolved. Further, any claims we assert against a perceived infringer could provoke these parties to assert counterclaims against us alleging that we have infringed their patents. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

In addition, our licensed patents and patent applications, and patents and patent applications that we may apply for, own or license in the future, could face other challenges, such as interference proceedings, opposition proceedings, re-examination proceedings and other forms of post-grant review. Any of these challenges, if successful, could result in the invalidation of, or in a narrowing of the scope of, any of our licensed patents and patent applications and patents and patent applications that we may apply for, own or license in the future subject to challenge. Any of these challenges, regardless of their success, would likely be time-consuming and expensive to defend and resolve and would divert our management and scientific personnel's time and attention.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates or potential products.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity and is costly, time-consuming and inherently uncertain. For example, the U.S. previously enacted and is currently implementing wide-ranging patent reform legislation. Specifically, on September 16, 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act") was signed into law and included a number of significant changes to U.S. patent law, and many of the provisions became effective in March 2013. However, it may take the courts years to interpret the provisions of the Leahy-Smith Act, and the implementation of the statute could increase the uncertainties and costs surrounding the prosecution of our licensed and future patent applications and the enforcement or defense of our licensed and future patents, all of which could have a material adverse effect on our business, financial condition and results of operations.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. The recent decision by the U.S. Supreme Court in *Association for Molecular Pathology v. Myriad Genetics, Inc.* precludes a claim to a nucleic acid having a stated nucleotide sequence which is identical to a sequence found in nature and unmodified. We are currently not aware of an immediate impact of this decision on our patents or patent applications which contain modifications that we believe are not found in nature. However, this decision has yet to be clearly interpreted by courts and by the USPTO. We cannot make assurances that the interpretations of this decision or subsequent rulings will not adversely impact our patents or patent applications. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we might obtain in the future.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates throughout the world would be prohibitively expensive. Competitors may use our licensed and owned technologies in jurisdictions where we have not licensed or obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain or license patent protection, but where patent enforcement is not as strong as that in the U.S. These products may compete with our product candidates in jurisdictions where we do not have any issued or licensed patents, and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our licensed patents and future patents we may own, or marketing of competing products in violation of our proprietary rights generally. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our licensed and owned intellectual property both in the U.S. and abroad. For example, China currently affords less protection to a company's intellectual property than some other jurisdictions. As such, the lack of strong patent and other intellectual property protection in China may significantly increase our vulnerability regarding unauthorized disclosure or use of our intellectual property and undermine our competitive position. Proceedings to enforce our future patent rights, if any, in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

In order to protect our proprietary and licensed technology and processes, we rely in part on confidentiality agreements with our corporate partners, employees, consultants, manufacturers, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of our confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We expect to employ individuals who were previously employed at other pharmaceutical companies. Although we have no knowledge of any such claims against us, we may be subject to claims that us or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

We may be subject to claims challenging the inventorship of our licensed patents, any future patents we may own and other intellectual property.

Although we are not currently experiencing any claims challenging the inventorship of our licensed patents or our licensed or owned intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our licensed patents or other licensed or owned intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business, financial condition and results of operations. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

If we do not obtain additional protection under the Hatch-Waxman Amendments and similar foreign legislation extending the terms of our licensed patents and any future patents we may own, our business, financial condition and results of operations may be materially and adversely affected.

Depending upon the timing, duration and specifics of FDA regulatory approval for our product candidates, one or more of our licensed U.S. patents or future U.S. patents that we may license or own may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during drug development and the FDA regulatory review process. This period is generally one-half the time between the effective date of an IND (falling after issuance of the patent) and the submission date of a New Drug Application ("NDA"), plus the time between the submission date of an NDA and the approval of that application. Patent term restorations, however, cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval by the FDA.

The application for patent term extension is subject to approval by the USPTO, in conjunction with the FDA. It takes at least six months to obtain approval of the application for patent term extension. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain earlier approval of competing products, and our ability to generate revenues could be materially adversely affected.

Risks Related to Government Regulation

We are very early in our development efforts. All of our product candidates are still in preclinical development. If we are unable to advance our product candidates to clinical development, obtain regulatory approval and ultimately commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

We are very early in our development efforts, and all of our product candidates are still in preclinical development. We have invested substantially all of our efforts and financial resources in the identification and preclinical development of antisense oligonucleotide therapies ("ASOs"), including the development program for the treatment of Huntington's Disease. Our ability to generate product revenues, which it does not expect will occur for many years, if ever, will depend on the successful development and eventual commercialization of our product candidates, which may never occur. We currently generate no revenue from sales of any products, and we may never be able to develop or commercialize a marketable product. In addition, certain of our product candidate development programs contemplate the development of companion diagnostics, which are assays or tests to identify an appropriate patient population. Companion diagnostics are subject to regulation as medical devices and must themselves be approved for marketing by the FDA or certain other foreign regulatory agencies before we may commercialize our product candidates. The success of our product candidates will depend on several factors, including the following:

- successful completion of preclinical studies;
- approval of INDs for our planned clinical trials or future clinical trials;
- successful enrollment in, and completion of, clinical trials;
- successful development of companion diagnostics for use with certain of our product candidates;
- receipt of regulatory approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers for clinical supply and commercial manufacturing;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of the product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining third-party insurance coverage and adequate reimbursement;
- enforcing and defending intellectual property rights and claims; and
- maintaining a continued acceptable safety profile of the product candidates following approval, if approved.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

Furthermore, the FDA has relatively limited experience with nucleic acid therapeutics, particularly PNAs, which may increase the complexity, uncertainty and length of the regulatory review process for our product candidates. To date, the FDA has approved few nucleic acid therapeutics for marketing and commercialization, and the FDA and our foreign counterparts have not yet established any definitive policies, practices or guidelines specifically in relation to these drugs. The lack of policies, practices or guidelines specific to nucleic acid therapeutics may hinder or slow review by the FDA of any regulatory filings that we may submit. Moreover, the FDA may respond to these submissions by defining requirements we may not have anticipated. Such responses could lead to significant delays in the development of our product candidates. In addition, because there may be approved treatments for some of the diseases for which we may seek approval, in order to receive regulatory approval, we may need to demonstrate through clinical trials that the product candidates we develop to treat these diseases, if any, are not only safe and effective, but safer or more effective than existing products. Furthermore, in recent years, there has been increased public and political pressure on the FDA with respect to the approval process for new drugs, and the FDA's standards, especially regarding drug safety, appear to have become more stringent. As a result of the foregoing factors, we may never receive regulatory approval to market and commercialize any product candidate.

Preclinical and clinical trials are expensive, time-consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials.

All of our product candidates are still in the preclinical stage, and their risk of failure is high. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned INDs in the U.S., or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. It is also impossible to predict when or if any of our product candidates will complete clinical trials evaluating their safety and effectiveness in humans or will receive regulatory approval. To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our PATrOL™ platform and product candidates are safe and effective in humans for use in each target indication. To date, we have never advanced a product candidate into a clinical trial. Preclinical and clinical testing is expensive and can take many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the preclinical or clinical trial process. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business, financial condition and results of operations.

Additionally, the results of preclinical studies and future clinical trials of product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. Many companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier studies. Similarly, our future clinical trial results may not be successful for these or other reasons.

This product candidate development risk is heightened by any changes in the anticipated clinical trials compared to the completed clinical trials. As product candidates are developed from preclinical through early to late stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and methods of administration, are altered along the way in an effort to optimize processes and results. While these types of changes are common and are intended to optimize the product candidates for late stage clinical trials, approval and commercialization, such changes carry the risk that they will not achieve these intended objectives.

Any of these changes could make the results of our anticipated clinical trials or other future clinical trials we may initiate less predictable and could cause our product candidates to perform differently, including causing toxicities, which could delay completion of our clinical trials, delay approval of our product candidates, and/or jeopardize our ability to commence product sales and generate revenues.

We may rely on third parties to conduct investigator-sponsored clinical trials of our product candidates. Any failure by a third party to meet our obligations with respect to the clinical development of our product candidates may delay or impair our ability to obtain regulatory approval for other product candidates.

We may rely on academic and private non-academic institutions to conduct and sponsor preclinical and clinical trials relating to our product candidates. We will not control the design or conduct of the investigator-sponsored trials, and it is possible that the FDA or non-U.S. regulatory authorities will not view these investigator-sponsored trials as providing adequate support for future preclinical and clinical trials, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results. For example, we collaborate with, and rely on, academic centers to conduct preclinical and non-investigator-sponsored research and it is possible that the interests of such academic centers may not be aligned with our interests.

Such arrangements will likely provide us certain information rights with respect to the investigator-sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory filings, resulting from the investigator-sponsored trials. However, we would not have control over the timing and reporting of the data from investigator-sponsored trials, nor would we own the data from the investigator-sponsored trials. If we are unable to confirm or replicate the results from the investigator-sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development of our product candidates. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data proves to be inadequate compared to the first-hand knowledge we might have gained had the investigator-sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future preclinical or clinical trials ourselves may be adversely affected.

Additionally, the FDA or non-U.S. regulatory authorities may disagree with the sufficiency of our right of reference to the preclinical, manufacturing or clinical data generated by these investigator-sponsored trials, or our interpretation of preclinical, manufacturing or clinical data from these investigator-sponsored trials. If so, the FDA or other non-U.S. regulatory authorities may require us to obtain and submit additional preclinical, manufacturing, or clinical data before we may initiate our anticipated trials and/or may not accept such additional data as adequate to initiate our anticipated trials.

Our product candidates may cause undesirable side effects that could delay or prevent their regulatory approval or commercialization or have other significant adverse implications on our business, financial condition and results of operations.

Undesirable side effects observed in preclinical studies or in clinical trials with our product candidates could interrupt, delay or halt their development and could result in the denial of regulatory approval by the FDA, the EMA or comparable foreign authorities for any or all targeted indications or adversely affect the marketability of any product candidates developed using our PATrOL™ platform that receive regulatory approval. In turn, this could eliminate or limit our ability to commercialize our product candidates.

Our product candidates may exhibit adverse effects in preclinical toxicology studies and adverse interactions with other drugs. There are also risks associated with additional requirements the FDA, the EMA or comparable foreign authorities may impose for marketing approval with regard to a particular disease.

Our product candidates may require a risk management program that could include patient and healthcare provider education, usage guidelines, appropriate promotional activities, a post-marketing observational study and ongoing safety and reporting mechanisms, among other requirements. Prescribing could be limited to physician specialists or physicians trained in the use of the drug, or could be limited to a more restricted patient population. Any risk management program required for approval of our product candidates could potentially have an adverse effect on our business, financial condition and results of operations.

Undesirable side effects involving our product candidates may have other significant adverse implications on our business, financial condition and results of operations. For example:

- we may be unable to obtain additional financing on acceptable terms, if at all;
- our collaborators may terminate any development agreements covering these product candidates;
- if any development agreements are terminated, we may determine not to further develop the affected product candidates due to resource constraints and may not be able to establish additional collaborations for their further development on acceptable terms, if at all;
- if we were to later continue the development of these product candidates and receive regulatory approval, earlier findings may significantly limit their marketability and thus significantly lower our potential future revenues from their commercialization;
- we may be subject to product liability or stockholder litigation; and
- we may be unable to attract and retain key employees.

In addition, if any of our product candidates receive marketing approval and we or others later identify undesirable side effects caused by the product:

- regulatory authorities may withdraw their approval of the PATrOL™ platform and the product, or we or our partners may decide to cease marketing and sale of the product voluntarily;
- we may be required to change the way the product is administered, conduct additional preclinical studies or additional clinical trials after initial clinical trials regarding the product, change the labeling of the product, or change the product's manufacturing facilities; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product and could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating significant revenues from the sale of the product.

Delays in the commencement or completion of clinical trials could result in increased costs to us and delay our ability to establish strategic collaborations.

Delays in the commencement or completion of clinical trials could significantly impact our drug development costs. We do not know whether anticipated clinical trials will begin on time or be completed on schedule, if at all. The commencement of clinical trials can be delayed for a variety of reasons, including, but not limited to, delays related to:

- obtaining regulatory approval to commence one or more clinical trials;
- reaching agreement on acceptable terms with prospective third-party contract research organizations ("CROs") and clinical trial sites;
- manufacturing sufficient quantities of a product candidate or other materials necessary to conduct clinical trials;
- obtaining institutional review board approval to conduct one or more clinical trials at a prospective site;
- recruiting and enrolling patients to participate in one or more clinical trials; and
- the failure of our collaborators to adequately resource our product candidates due to their focus on other programs or as a result of general market conditions.

In addition, once a clinical trial has begun, it may be suspended or terminated by us, our collaborators, the institutional review boards or data safety monitoring boards charged with overseeing our clinical trials, the FDA, the EMA or comparable foreign authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- inspection of the clinical trial operations or clinical trial site by the FDA, the EMA or comparable foreign authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues;
- lack of adequate funding to continue the clinical trials; and
- lack of patient enrollment in clinical studies.

If we experience delays in the completion or termination of any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to commence product sales and generate product revenues from any of our product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs and slow down our product candidate development and approval process. Delays in completing our clinical trials could also allow our competitors to obtain marketing approval before we do or shorten the patent protection period during which we may have the exclusive right to commercialize our product candidates. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

If we experience delays in the enrollment of patients in our clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other regulatory authorities. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

If we fail to enroll and maintain the number of patients for which the clinical trial was designed, the statistical power of that clinical trial may be reduced, which would make it harder to demonstrate that the product candidate being tested in such clinical trial is safe and effective. Additionally, enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause our value to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients for any of our future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

We intend to rely on third parties to conduct our preclinical studies and clinical trials and perform other tasks. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business, financial condition and results of operations could be substantially harmed.

We intend to rely upon third-party CROs, medical institutions, clinical investigators and contract laboratories to monitor and manage data for our ongoing preclinical and anticipated clinical programs. Nevertheless, we maintain responsibility for ensuring that each of our preclinical studies are, and anticipated clinical studies will be, conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on these third parties does not relieve the Company of our regulatory responsibilities. The Company and our CROs and other vendors are required to comply with current requirements on cGMP, good clinical practices ("GCP") and GLP, which are a collection of laws and regulations enforced by the FDA, the EMA and comparable foreign authorities for all of our product candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections of preclinical study and clinical trial sponsors, principal investigators, preclinical study and clinical trial sites, and other contractors. If we or any of our CROs or vendors fails to comply with applicable regulations, the data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign authorities may require us to perform additional preclinical studies and clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced consistent with cGMP regulations. Our failure to comply with these regulations may require it to repeat clinical trials, which would delay the development and regulatory approval processes.

We may also not be able to enter into arrangements with CROs on commercially reasonable terms, or at all. In addition, our CROs will not be our employees, and except for remedies available to us under our agreements with such CROs, we will not be able to control whether or not they devote sufficient time and resources to our ongoing preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. CROs may also generate higher costs than anticipated. As a result, our business, financial condition and results of operations and the commercial prospects for our product candidates could be materially and adversely affected, our costs could increase, and our ability to generate revenue could be delayed.

Switching or adding additional CROs, medical institutions, clinical investigators or contract laboratories involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work replacing a previous CRO. As a result, delays occur, which can materially impact our ability to meet our desired development timelines. There can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition or results of operations.

Our product candidates are subject to extensive regulation under the FDA, the EMA or comparable foreign authorities, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, export, marketing and distribution of our product candidates are subject to extensive regulation by the FDA and other U.S. regulatory agencies, the EMA or comparable authorities in foreign markets. In the U.S., neither us nor our collaborators are permitted to market our product candidates until we or our collaborators receive approval of an NDA from the FDA or receive similar approvals abroad. The process of obtaining these approvals is expensive, often takes many years, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. Approval policies or regulations may change and may be influenced by the results of other similar or competitive products, making it more difficult for us to achieve such approval in a timely manner or at all. Any guidance that may result from recent FDA advisory panel discussions may make it more expensive to develop and commercialize such product candidates. In addition, as a company, we have not previously filed NDAs with the FDA or filed similar applications with other foreign regulatory agencies. This lack of experience may impede our ability to obtain FDA or other foreign regulatory agency approval in a timely manner, if at all, for our product candidates for which development and commercialization is our responsibility.

Despite the time and expense invested, regulatory approval is never guaranteed. The FDA, the EMA or comparable foreign authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- a product candidate may not be deemed safe or effective;
- agency officials of the FDA, the EMA or comparable foreign authorities may not find the data from non-clinical or preclinical studies and clinical trials generated during development to be sufficient;
- the FDA, the EMA or comparable foreign authorities may not approve our third-party manufacturers' processes or facilities; or
- the FDA, the EMA or a comparable foreign authority may change our approval policies or adopt new regulations.

Our inability to obtain these approvals would prevent us from commercializing our product candidates.

The FDA, the NIH and the EMA have demonstrated caution in their regulation of gene therapy treatments, and ethical and legal concerns about gene therapy and genetic testing may result in additional regulations or restrictions on the development and commercialization of our product candidates, which may be difficult to predict.

The FDA, National Institutes of Health ("NIH") and the EMA have each expressed interest in further regulating biotechnology, including gene therapy and genetic testing. For example, the EMA advocates a risk-based approach to the development of a gene therapy product. Agencies at both the federal and state level in the United States, as well as U.S. congressional committees and other governments or governing agencies, have also expressed interest in further regulating the biotechnology industry. Such action may delay or prevent commercialization of some or all of our product candidates.

Regulatory requirements in the U.S. and in other jurisdictions governing gene therapy products have changed frequently and may continue to change in the future. The FDA established the Office of Cellular, Tissue and Gene Therapies within its Center for Biologics Evaluation and Research to consolidate the review of gene therapy and related products, and established the Cellular, Tissue and Gene Therapies Advisory Committee to advise this review. Prior to submitting an IND, our human clinical trials will be subject to review by the NIH Office of Biotechnology Activities ("OBA") Recombinant DNA Advisory Committee (the "RAC"). Following an initial review, RAC members make a recommendation as to whether the protocol raises important scientific, safety, medical, ethical or social issues that warrant in-depth discussion at the RAC's quarterly meetings. Even though the FDA decides whether individual gene therapy protocols may proceed under an IND, the RAC's recommendations are shared with the FDA and the RAC public review process, if undertaken, can delay the initiation of a clinical trial, even if the FDA has reviewed the trial design and details and has not objected to its initiation or has notified the sponsor that the study may begin. Conversely, the FDA can put an IND on a clinical hold even if the RAC has provided a favorable review or has recommended against an in-depth, public review. Moreover, under guidelines published by the NIH, patient enrollment in our future gene silencing clinical trials cannot begin until the investigator for such clinical trial has received a letter from the OBA indicating that the RAC review process has been completed; and Institutional Biosafety Committee ("IBC") approval as well as all other applicable regulatory authorizations have been obtained. In addition to the government regulators, the IBC and IRB of each institution at which we will conduct clinical trials of our product candidates, or a central IRB if appropriate, would need to review the proposed clinical trial to assess the safety of the trial. In addition, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other oversight bodies to change the requirements for approval of any of our product candidates. Similarly, the EMA governs the development of gene therapies in the European Union and may issue new guidelines concerning the development and marketing authorization for gene therapy products and require that we comply with these new guidelines. These regulatory review agencies and committees and the new requirements or guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory agencies and committees and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our or our collaborators' ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all.

Even if our product candidates receive regulatory approval in the U.S., it may never receive approval or commercialize our products outside of the U.S.

In order to market any products outside of the U.S., we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the U.S. as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay seeking or obtaining such approval would impair our ability to develop foreign markets for our product candidates.

Even if any of our product candidates receive regulatory approval, our product candidates may still face future development and regulatory difficulties.

If any of our product candidates receive regulatory approval, the FDA, the EMA or comparable foreign authorities may still impose significant restrictions on the indicated uses or marketing of the product candidates or impose ongoing requirements for potentially costly post-approval studies and trials. In addition, regulatory agencies subject a product, our manufacturer and the manufacturer's facilities to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, our collaborators or us, including requiring withdrawal of the product from the market. Our product candidates will also be subject to ongoing FDA, EMA or comparable foreign authorities' requirements for the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. If our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or other notices of possible violations;
- impose civil or criminal penalties or fines or seek disgorgement of revenue or profits;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us or our collaborators;
- withdraw any regulatory approvals;
- impose restrictions on operations, including costly new manufacturing requirements, or shut down our manufacturing operations; or
- seize or detain products or require a product recall.

The FDA, the EMA and comparable foreign authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA, the EMA and comparable foreign authorities strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA, the EMA or comparable foreign authorities as reflected in the product's approved labeling. If we receive marketing approval for our product candidates for our proposed indications, physicians may nevertheless use our products for their patients in a manner that is inconsistent with the approved label, if the physicians personally believe in their professional medical judgment that our products could be used in such manner. However, if we are found to have promoted our product candidates, if approved, for any off-label uses, the federal government could levy civil, criminal or administrative penalties, and seek fines against us. Such enforcement has become more common in the industry. The FDA, the EMA or comparable foreign authorities could also request that we enter into a consent decree or a corporate integrity agreement, or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business, financial condition and results of operations.

We and our potential contract manufacturers are subject to significant regulation with respect to manufacturing our product candidates. The manufacturing facilities on which we will rely may not continue to meet regulatory requirements.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our potential contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our potential contract manufacturers must supply all necessary documentation in support of an NDA or marketing authorization application ("MAA") on a timely basis and must adhere to GLP and cGMP regulations enforced by the FDA, the EMA or comparable foreign authorities through their facilities inspection program. Some of our potential contract manufacturers may not have produced a commercially approved pharmaceutical product and therefore may not have obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our potential third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we plan to oversee the contract manufacturers, we cannot control the manufacturing process of, and will be completely dependent on, our contract manufacturing partners for compliance with applicable regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the product candidates may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our potential third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly or time consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we may contract could materially harm our business, financial condition and results of operations.

If we or any of our potential third-party manufacturers fail to maintain regulatory compliance, the FDA, the EMA or comparable foreign authorities can impose regulatory sanctions including, among other things, refusal to approve a pending application for a product candidate, withdrawal of an approval, or suspension of production. As a result, our business, financial condition and results of operations may be materially and adversely affected.

Additionally, if supply from one manufacturer is interrupted, an alternative manufacturer would need to be qualified through an NDA supplement or MAA variation, or equivalent foreign regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies or trials if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur higher costs and could cause the delay or termination of clinical trials, regulatory submissions, required approvals, or commercialization of our product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

Current and future legislation may increase the difficulty and cost of commercializing our product candidates and may affect the prices we may obtain if our product candidates are approved for commercialization.

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

In the U.S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”) changed the way Medicare covers and pays for pharmaceutical products. Cost reduction initiatives and other provisions of this legislation could limit the coverage and reimbursement rate that we receive for any of our approved product candidates. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively the “ACA”), was enacted. The ACA was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The ACA increased manufacturers’ rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate amount for both branded and generic drugs and revised the definition of “average manufacturer price” (“AMP”), which may also increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The legislation also expanded Medicaid drug rebates and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the rebates due on those drugs. The Centers for Medicare & Medicaid Services, which administers the Medicaid Drug Rebate Program, also has proposed to expand Medicaid rebates to the utilization that occurs in the territories of the U.S., such as Puerto Rico and the Virgin Islands. Further, beginning in 2011, the ACA imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Legislative and regulatory proposals have been introduced at both the state and federal level to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products.

There have been recent public announcements by members of the U.S. Congress, President Trump and his administration regarding their plans to repeal and replace the ACA and Medicare. For example, on December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act of 2017, which, among other things, eliminated the individual mandate requiring most Americans (other than those who qualify for a hardship exemption) to carry a minimum level of health coverage, effective January 1, 2019. We are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing approval testing and other requirements.

Additionally, there has been heightened governmental scrutiny in the U.S. of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further 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. Further, the Trump administration released a "Blueprint," or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. While some 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.

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

In Europe, the United Kingdom has indicated its intent to withdraw from the European Union in the future. A significant portion of the regulatory framework in the United Kingdom is derived from the regulations of the European Union. We cannot predict what consequences the withdrawal of the United Kingdom from the European Union, if it occurs, might have on the regulatory frameworks of the United Kingdom or the European Union, or on our future operations, if any, in these jurisdictions.

Changes in government funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, properly administer drug innovation, or prevent our product candidates from being developed or commercialized, which could negatively impact our business, financial condition and results of operations.

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

In December 2016, the 21st Century Cures Act was signed into law. This new legislation is designed to advance medical innovation and empower the FDA with the authority to directly hire positions related to drug and device development and review. However, government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies. These budgetary pressures may result in a reduced ability by the FDA to perform their respective roles; including the related impact to academic institutions and research laboratories whose funding is fully or partially dependent on both the level and timing of funding from government sources.

Disruptions at the FDA and other agencies may also slow the time necessary for our product candidates to be reviewed or approved by necessary government agencies, which could adversely affect our business, financial condition and results of operations.

We are subject to "fraud and abuse" and similar laws and regulations, and a failure to comply with such regulations or prevail in any litigation related to noncompliance could harm our business, financial condition and results of operations.

In the U.S., we are subject to various federal and state healthcare "fraud and abuse" laws, including anti-kickback laws, false claims laws and other laws intended, among other things, to reduce fraud and abuse in federal and state healthcare programs. The federal Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer, or a party acting on its behalf, to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce the referral of business, including the purchase, order or prescription of a particular drug, or other good or service for which payment in whole or in part may be made under a federal healthcare program, such as Medicare or Medicaid. Although we seek to structure our business arrangements in compliance with all applicable requirements, these laws are broadly written, and it is often difficult to determine precisely how the law will be applied in specific circumstances. Accordingly, it is possible that our practices may be challenged under the federal Anti-Kickback Statute.

The federal False Claims Act prohibits anyone from, among other things, knowingly presenting or causing to be presented for payment to the government, including the federal healthcare programs, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services that were not provided as claimed, or claims for medically unnecessary items or services. Under the Health Insurance Portability and Accountability Act of 1996, we are prohibited from knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors, or 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 to obtain money or property of any healthcare benefit program. Violations of fraud and abuse laws may be punishable by criminal or civil sanctions, including penalties, fines or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the government under the federal False Claims Act as well as under the false claims laws of several states.

Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payors. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement, we could be subject to penalties.

Neither the government nor the courts have provided definitive guidance on the application of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. If we are found in violation of one of these laws, we could be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from governmental funded federal or state healthcare programs and the curtailment or restructuring of our operations. If this occurs, our business, financial condition and results of operations may be materially adversely affected.

If we face allegations of noncompliance with the law and encounter sanctions, our reputation, revenues and liquidity may suffer, and any of our product candidates that are ultimately approved for commercialization could be subject to restrictions or withdrawal from the market.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to generate revenues from any of our product candidates that are ultimately approved for commercialization. If regulatory sanctions are applied or if regulatory approval is withdrawn, our business, financial condition and results of operations will be adversely affected. Additionally, if we are unable to generate revenues from product sales, our potential for achieving profitability will be diminished and our need to raise capital to fund our operations will increase.

Risks Related to Our Common Stock

The market price of our common stock is expected to be volatile

The trading price of our stock is likely to be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- our ability to conduct and achieve positive outcomes from our preclinical activities on the PATrOL™ platform and disease specific programs;
- results from, and any delays in, anticipated in-vitro or in-vivo preclinical studies;
- contracting with third parties such as academic institutions, and various CROs who will perform such studies, or the potential lack of performance of such organizations;
- acceptance of INDs by the FDA or similar regulatory filing by comparable foreign regulatory authorities for the conduct of clinical trials of our product candidates and our proposed design of future clinical trials;
- clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain, so failure can occur at any time during the clinical trial process;
- delays in publications of research findings;
- significant lawsuits, including patent or stockholder litigation;
- inability to obtain additional funding or funding on favorable terms;
- failure to successfully develop and commercialize our product candidates;
- changes in laws or regulations applicable to our product candidates;
- inability to obtain adequate product supply for our product candidates, or the inability to do so at acceptable prices or in an acceptable timeframe;
- unanticipated serious safety concerns related to our PATrOL™ platform or any of our product candidates;
- adverse regulatory decisions;
- introduction of new products or technologies by our competitors;
- adverse events or results for our competitors or our product candidate target areas that could generally adversely affect us our or our industry;
- failure to meet or exceed drug development or financial projections we provide to the public;
- failure to meet or exceed the estimates, expectations and projections of the investment community and our stockholders;

- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our licensed and owned technologies;
- additions or departures of key scientific or management personnel;
- changes in the market valuations of similar companies;
- general economic and market conditions and overall fluctuations in the U.S. equity market;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- period-to-period fluctuations in our financial results;
- material weakness in our internal control over financial reporting, which, while we believe we have taken appropriate steps to remediate such material weakness, there can be no assurance that the steps we are taking will be sufficient to remediate our material weakness or prevent future material weaknesses or significant deficiencies from occurring;
- changes in the structure of health care payments;
- changes in the Nasdaq listing of our stock; and
- recommendations of equity analysts covering our stock.

In addition, the stock market, and equity values of small pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. Further, a decline in the financial markets and related factors beyond our control may cause our stock price to decline rapidly and unexpectedly.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

In connection with the preparation of our financial statements, our management and the audit committee of our board of directors determined that our accounting treatment and valuations pertaining to the PATrOL™ technology license should be modified. This change in accounting treatment resulted in an increase in total operating expenses of approximately $0.9 million on our Consolidated Statements of Operations and a decrease in intangible assets of approximately $1.5 million on our Consolidated Balance Sheet. In connection with the valuation adjustments to the PATrOL™ technology license, we also determined that valuations pertaining to certain share-based awards should also be adjusted. This change in valuation to share-based awards resulted in a decrease in total operating expenses of approximately $0.3 million on our Consolidated Statements of Operations. If we are required to restate any of our financial statements in the future due to our inability to adequately remedy the issues that gave rise to these modifications or for any other reason, we may be subject to regulatory penalties and investors could lose confidence in the accuracy and completeness of our financial statements, which could cause our share price to decline.

Our management owns a significant percentage of our stock and is able to exert significant control over matters subject to stockholder approval.

Dr. Stephan, our President, Chief Executive Officer and a director of us, holds a significant number of shares of our outstanding common stock and an option to purchase additional shares of common stock. Accordingly, Dr. Stephan has the ability to influence us through his ownership position.

This significant concentration of stock ownership may adversely affect the trading price for our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. As a result, Dr. Stephan could significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. Dr. Stephan may be able to determine all matters requiring stockholder approval. The interests of these stockholders may not always coincide with our interests or the interests of other stockholders. This may also prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interests as one of our stockholders, and he may act in a manner that advances his best interests and not necessarily those of other stockholders, including seeking a premium value for his common stock, and might affect the prevailing market price for our common stock.

Our internal control over financial reporting may not meet the standards required by Section 404 of the Sarbanes-Oxley Act, and failure to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act, could have a material adverse effect on our business and share price.

Our management is required to report on the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. We expect that compliance with these rules and regulations will continue to substantially increase our legal and financial compliance costs and will make some activities more time-consuming and costly, and our management and other personnel will devote a substantial amount of time to these compliance requirements.

In connection with the implementation of the necessary procedures and practices related to internal control over financial reporting, we may identify material weaknesses that we may not be able to remediate in time to meet the deadline imposed by the Sarbanes-Oxley Act for compliance with the requirements of Section 404. In addition, we may encounter problems or delays in completing the implementation of any improvements and receiving a favorable attestation in connection with the attestation provided by our independent registered public accounting firm, if and when required. Failure to achieve and maintain an effective internal control environment could have a material adverse effect on our business, financial condition and results of operations and could limit our ability to report our financial results accurately and in a timely manner.

In connection with an evaluation of the effectiveness of our disclosure controls and procedures, our chief executive officer ("CEO") and chief financial officer ("CFO") concluded that our disclosure controls and procedures were not effective as of September 30, 2019 due to a material weakness in our internal control over financial reporting due to a lack of expertise in complex accounting transactions. While our CEO and CFO believe that this material weakness has likely been remedied because we hired a financial accounting consultant to provide certain accounting advisory services, there can be no assurance that these steps will be sufficient to remediate our material weakness or prevent future material weaknesses from occurring.

We may take advantage of specified reduced disclosure requirements applicable to a "smaller reporting company" under Regulation S-K, and the information that we provide to stockholders may be different than they might receive from other public companies.

We are a "smaller reporting company," as defined under Regulation S-K. As a smaller reporting company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include, among other things, scaled disclosure requirements, including about our executive compensation arrangements.

We intend to continue to take advantage of certain of the scaled disclosure requirements of smaller reporting companies. We may continue to take advantage of these allowances until we are no longer a smaller reporting company. We will cease to be a smaller reporting company if we have (i) more than $250 million in market value of our shares held by non-affiliates as of the last business day of our second fiscal quarter or (ii) more than $100 million of annual revenues in our most recent fiscal year completed before the last business day of our second fiscal quarter and a market value of our shares held by non-affiliates more than $700 million as of the last business day of our second fiscal quarter. We may choose to take advantage of some but not all of these scaled disclosure requirements. Therefore, the information that we provide stockholders may be different than one might get from other public companies. Further, if some investors find our shares of common stock less attractive as a result, there may be a less active trading market for our shares of common stock and the market price of such shares of common stock may be more volatile.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline.

Sales of a substantial number of shares of our common stock in the public market by our stockholders, future issuances of our common stock or rights to purchase our common stock, could cause our stock price to fall.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States are the exclusive forums for substantially all disputes between us and our stockholders other than actions arising under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising under the General Corporation Law of the State of Delaware (the "DGCL"), our amended and restated certificate of incorporation or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

These exclusive-forum provisions do not apply to claims under the Securities Act, the Exchange Act or any other claims for which the federal courts have exclusive jurisdiction.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, it may incur additional costs associated with resolving the dispute in other jurisdictions, which could harm our business.

We are subject to securities class action litigation and derivative shareholder litigation. If an unfavorable ruling were to occur, there exists the possibility of a material adverse impact on us.

On February 14, 2018, plaintiff, Jeevesh Khanna, commenced an action in the Southern District of New York, against Ohr and several current and former officers and directors, alleging that they violated federal securities laws between June 24, 2014 and January 4, 2018. On August 7, 2018, the lead plaintiffs, now George Lehman and Insured Benefit Plans, Inc. filed an amended complaint, stating the class period to be April 8, 2014 through January 4, 2018. The plaintiffs did not quantify any alleged damages in their complaint but, in addition to attorneys' fees and costs, they seek to maintain the action as a class action and to recover damages on behalf of themselves and other persons who purchased or otherwise acquired Ohr common stock during the putative class period and purportedly suffered financial harm as a result. We and the individuals dispute these claims and intend to defend the matter vigorously. On September 17, 2018, Ohr filed a motion to dismiss the complaint. On September 20, 2019, the Court entered an order granting the defendants' motion to dismiss. On October 23, 2019, the plaintiffs filed a notice of appeal of that order dismissing the action and other related orders by the Court. Briefing on the appeal is currently scheduled for the first half of 2020. This litigation could result in substantial costs and a diversion of management's resources and attention, which could harm our business and the value of our common stock.

On May 3, 2018, plaintiff Adele J. Barke, derivatively on behalf of Ohr, commenced an action against certain former directors of Ohr, including Michael Ferguson, Orin Hirschman, Thomas M. Riedhammer, June Almenoff and Jason S. Slakter in the Supreme Court, State of New York, alleging that the action was brought in the right and for the benefit of Ohr seeking to remedy their "breach of fiduciary duties, corporate waste and unjust enrichment that occurred between June 24, 2014 and the present." It does not quantify any alleged damages. We and the individuals dispute these claims and intend to defend the matter vigorously. Such litigation has been stayed pursuant to a stipulation by the parties, which has been so ordered by the court, pending a decision in the Southern District case on the motion to dismiss, but that status could change. This litigation could result in substantial costs and a diversion of management's resources and attention, which could harm our business and the value of our common stock.

On March 20, 2019, a putative class action lawsuit was filed in the United States District Court for District of Delaware naming as defendants Ohr and its board of directors, Legacy NeuBase and Ohr Acquisition Corp., captioned *Wheby v. Ohr Pharmaceutical, Inc., et al*, Case No. 1:19-cv-00541-UNA (the "Wheby Action"). The plaintiffs in the Wheby Action allege that the preliminary joint proxy/prospectus statement filed by Ohr with the SEC on March 8, 2019 contained false and misleading statements and omitted material information in violation of Section 14(a) of the Exchange Act and SEC Rule 14a-9 promulgated thereunder, and further that the individual defendants are liable for those alleged misstatements and omissions under Section 20(a) of the Exchange Act. The complaint in the Wheby Action has not been served on, nor was service waived by, any of the named defendants in that action. The action seeks, among other things, to rescind the Merger or an award of damages, and an award of attorneys' and experts' fees and expenses. The defendants dispute the claims raised in the Wheby Action. Management believes that the likelihood of an adverse decision from the sole remaining action is unlikely; however, the litigation could result in substantial costs and a diversion of management's resources and attention, which could harm our business and the value of our common stock.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of the Company more difficult and may prevent attempts by our stockholders to replace or remove our management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may significantly reduce the value of shares of our common stock to a potential acquirer or delay or prevent an acquisition or a change in management without the consent of our board of directors. The provisions in our amended and restated certificate of incorporation and amended and restated bylaws include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive rights of our board of directors to establish the authorized number of directors and to elect a director to fill a vacancy created by the expansion of our board of directors or the death, resignation, disqualification, retirement or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- a provision that directors may be removed by our stockholders only for cause;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;

- the ability of our board of directors to make, alter or appeal our amended and restated bylaws without obtaining stockholder approval;
- the affirmative vote of the holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of our capital stock entitled to vote generally in the election of directors is required to amend, alter, repeal or adopt any provision inconsistent with, several of the provisions of our amended and restated certificate of incorporation and amended and restated bylaws;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by our board of directors, chief executive officer or president, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- a restriction on the forum for certain litigation against us to Delaware; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

Certain provisions of the DGCL deter hostile takeovers. Specifically, Section 203 of the DGCL prohibits a Delaware corporation from engaging in a business combination with an "interested stockholder" for a period of three years following the date the person first became an interested stockholder, unless (with certain exceptions) the business combination or the transaction by which the person became an interested stockholder is approved in a prescribed manner. Generally, a "business combination" includes a merger, asset or stock sale, or certain other transactions resulting in a financial benefit to the interested stockholder. Generally, an "interested stockholder" is a person who, together with affiliates and associates, beneficially owns or within three years prior to becoming an "interested stockholder" did own, 15% or more of a corporation's outstanding voting stock. While this statute permits a corporation to opt out of these protective provisions in its certificate of incorporation, our certificate of incorporation does not include any such opt-out provision.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation provides that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the General Corporation Law of the State of Delaware, or the DGCL, our amended and restated certificate of incorporation and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.

- We are required to advance expenses actually and reasonably incurred by our directors and officers in connection with any proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined by a court of competent jurisdiction that such person is not entitled to indemnification.
- We will not be obligated pursuant to our amended and restated certificate of incorporation to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights to indemnification conferred in our amended and restated certificate of incorporation are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our amended and restated certificate of incorporation provisions to reduce our indemnification obligations to current or former directors or officers.

This indemnification policy could result in substantial expenditures by us, which we will be unable to recover.

Our pre-Merger net operating loss carryforwards and certain other tax attributes will likely be subject to limitations. The pre-Merger net operating loss carryforwards and certain other tax attributes of us may also be subject to limitations as a result of ownership changes resulting from the Merger.

In general, a corporation that undergoes an "ownership change," as defined in Section 382 of the Internal Revenue Code of 1986, as amended, is subject to limitations on its ability to utilize its pre-change net operating losses ("NOLs") to offset future taxable income (the "Section 382 Limitation"). Such an ownership change occurs if the aggregate stock ownership of certain stockholders, generally stockholders beneficially owning five percent or more of a corporation's common stock, applying certain look-through and aggregation rules, increases by more than 50 percentage points over such stockholders' lowest percentage ownership during the testing period, generally three years. Due to the ownership change of the Company upon completion of the Merger, our NOLs and certain other tax attributes will be subject to the Section 382 Limitation. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our NOLs and certain other tax attributes because of the Section 382 Limitation, which could have a material adverse effect on cash flow and results of operations. As of September 30, 2019, we estimated that we had approximately $6.4 million in NOL carryforwards. The company has not completed an analysis regarding the limitation of net operating loss carryforwards, however, it is likely that the Section 382 Limitation will cause a significant portion of our NOL carryforwards to never be utilized. In addition, if we are determined to have discontinued our historic business following the completion of the Merger, subject to certain exceptions, the Section 382 Limitation could eliminate all possibility of utilizing our NOL carryforwards.

We may never pay dividends on our common stock so any returns would be limited to the appreciation of our stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate we will declare or pay any cash dividends for the foreseeable future. In addition, the terms of any future debt agreements may preclude us from paying dividends. Any return to stockholders will therefore be limited to the appreciation of their stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We currently sublease approximately 2,200 square feet of office and wet lab space at our headquarters in downtown Pittsburgh, Pennsylvania. Our wet lab space is used in our research and development program activities in Pittsburgh, Pennsylvania and accommodates our anticipated workforce and near-term growth needs. The sublease terms are below the current prevailing market rate per square foot and for a term of one year, with one six month extension. We believe that our subleased facilities are generally well maintained and in good operating condition and that the space is suitable and sufficient for our operational needs.

ITEM 3. LEGAL PROCEEDINGS

We have become involved in certain legal proceedings and claims which arise in the normal course of business. If an unfavorable ruling were to occur, there exists the possibility of a material adverse impact on our results of operations, prospects, cash flows, financial position and brand.

On February 14, 2018, plaintiff, Jeevesh Khanna, commenced an action in the Southern District of New York, against Ohr and several current and former officers and directors, alleging that they violated federal securities laws between June 24, 2014 and January 4, 2018. On August 7, 2018, the lead plaintiffs, now George Lehman and Insured Benefit Plans, Inc. filed an amended complaint, stating the class period to be April 8, 2014 through January 4, 2018. The plaintiffs did not quantify any alleged damages in their complaint but, in addition to attorneys' fees and costs, they seek to maintain the action as a class action and to recover damages on behalf of themselves and other persons who purchased or otherwise acquired Ohr common stock during the putative class period and purportedly suffered financial harm as a result. We and the individuals dispute these claims and intend to defend the matter vigorously. On September 17, 2018, Ohr filed a motion to dismiss the complaint. On September 20, 2019, the Court entered an order granting the defendants' motion to dismiss. On October 23, 2019, the plaintiffs filed a notice of appeal of that order dismissing the action and other related orders by the Court. Briefing on the appeal is currently scheduled for the first half of 2020. This litigation could result in substantial costs and a diversion of management's resources and attention, which could harm our business and the value of our common stock.

On May 3, 2018, plaintiff Adele J. Barke, derivatively on behalf of Ohr, commenced an action against certain former directors of Ohr, including Michael Ferguson, Orin Hirschman, Thomas M. Riedhammer, June Almenoff and Jason S. Slakter in the Supreme Court, State of New York, alleging that the action was brought in the right and for the benefit of Ohr seeking to remedy their "breach of fiduciary duties, corporate waste and unjust enrichment that occurred between June 24, 2014 and the present." It does not quantify any alleged damages. We and the individuals dispute these claims and intend to defend the matter vigorously. Such litigation has been stayed pursuant to a stipulation by the parties, which has been so ordered by the court, pending a decision in the Southern District case on the motion to dismiss, but that status could change. This litigation could result in substantial costs and a diversion of management's resources and attention, which could harm our business and the value of our common stock.

On March 20, 2019, a putative class action lawsuit was filed in the United States District Court for District of Delaware naming as defendants Ohr and its board of directors, Legacy NeuBase, and Ohr Acquisition Corp., captioned *Wheby v. Ohr Pharmaceutical, Inc., et al*, Case No. 1:19-cv-00541-UNA (the "Wheby Action"). The plaintiffs in the Wheby Action allege that the preliminary joint proxy/prospectus statement filed by Ohr with the SEC on March 8, 2019 contained false and misleading statements and omitted material information in violation of Section 14(a) of the Exchange Act and SEC Rule 14a-9 promulgated thereunder, and further that the individual defendants are liable for those alleged misstatements and omissions under Section 20(a) of the Exchange Act. The complaint in the Wheby Action has not been served on, nor was service waived by, any of the named defendants in that action. The action seeks, among other things, to rescind the Merger or an award of damages, and an award of attorneys' and experts' fees and expenses. The defendants dispute the claims raised in the Wheby Action. Management believes that the likelihood of an adverse decision from the sole remaining action is unlikely; however, the litigation could result in substantial costs and a diversion of management's resources and attention, which could harm our business and the value of our common stock.

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 traded on the Nasdaq Capital Market under the symbol "NBSE." Before July 15, 2019, our common stock traded under the ticker symbol "OHRP". The daily market activity and closing prices of our common stock can be found at www.nasdaq.com.

On January 7, 2020, the last reported sales price for our common stock on the Nasdaq Capital Market was $7.43 per share, and we had 193 holders of record of our common stock. One of our shareholders is Cede & Co., a nominee for Depository Trust Company ("DTC"). Shares of common stock that are held by financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are considered to be held of record by Cede & Co. as one stockholder.

Equity Compensation Plan Information

The following table gives information as of September 30, 2019 about shares of our common stock that may be issued upon the exercise of options under our existing equity compensation plans:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)(1)	Weighted-average exercise price of outstanding options, warrants and rights (b)(2)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)(3)
Equity compensation plans approved by security holders (4)	3,038,560	$ 5.67	299,289
Equity compensation plans not approved by security holders (5)	3,337,406	$ 0.001	-
Total	6,375,966	$ 2.70	299,289

(1) Consists of options outstanding as of September 30, 2019 under the Ohr Pharmaceutical, Inc. 2019 Stock Incentive Plan (the "2019 Plan"), the NeuBase Therapeutics, Inc. 2018 Equity Incentive Plan (the "2018 Plan"), the Ohr Pharmaceutical, Inc. 2016 Consolidated Stock Incentive Plan (the "2016 Plan"), the Ohr Pharmaceutical, Inc. 2014 Stock Incentive Plan (the "2014 Plan") and the Ohr Pharmaceutical, Inc. 2009 Stock Incentive Plan.
(2) Consists of the weighted average exercise price of outstanding options as of September 30, 2019.
(3) Consists entirely of shares of common stock that remain available for future issuance under the 2019 Plan and the 2016 Plan as of September 30, 2019.
(4) The number of shares of our common stock available for issuance under the 2019 Plan will automatically increase on October 1st of each year, for a period of not more than ten years, beginning October 1, 2019 and ending on (and including) October 1, 2028 by the lesser of (a) 4.0% of the total number of shares of our common stock outstanding as of September 30th of the immediately preceding fiscal year, and (b) such number of shares of common stock determined by our board of directors.
(5) Consists of the 2018 Plan.

Unregistered Sales of Equity Securities and Use of Proceeds

Except as previously disclosed on a Current Report on Form 8-K filed with the SEC on July 12, 2019, as amended by a Current Report on Form 8-K/A filed with the SEC on July 17, 2019 regarding the Post-Merger Financing, there were no unregistered sales of common stock or other equity securities during the fiscal year ended September 30, 2019.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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

Disclosures Regarding Forward-Looking Statements

This report includes "forward-looking statements" within the meaning of Section 21E of the Exchange Act. Those statements include statements regarding the intent, belief or current expectations of the Company and its subsidiaries and our management team. Any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and actual results may differ materially from those projected in the forward-looking statements. These risks and uncertainties include but are not limited to those risks and uncertainties set forth in Item 1A of this Annual Report on Form 10-K. In light of the significant risks and uncertainties inherent in the forward-looking statements included in this Annual Report on Form 10-K, the inclusion of such statements should not be regarded as a representation by us or any other person that our objectives and plans will be achieved. Further, these forward-looking statements reflect our view only as of the date of this report. Except as required by law, we undertake no obligations to update any forward-looking statements and we disclaim any intent to update forward-looking statements after the date of this report to reflect subsequent developments. Accordingly, you should also carefully consider the factors set forth in other reports or documents that we file from time to time with the SEC.

Overview

As a result of the Merger, our going-forward operations will be primarily those of Legacy NeuBase. Accordingly, the results of operations reported for the fiscal years ended September 30, 2019 and 2018, in this Management's Discussion and Analysis are not indicative of the results of operations expected for future years due to the transition of our historic business operations to primarily those of Legacy NeuBase.

We are a biotechnology company focused on developing next generation therapies to treat rare genetic diseases and cancer caused by mutant genes. Given that perhaps every human disease has a genetic component, we believe that our differentiated platform technology has the potential for broad impact.

Mutated proteins resulting from errors in deoxyribonucleic acid ("DNA") sequences cause many rare genetic diseases and cancer. DNA in each cell of the body is transcribed into pre-RNA, which is then processed (spliced) into mRNA which is exported into the cytoplasm of the cell and translated into protein. This is termed the "central dogma" of biology. Therefore, when errors in a DNA sequence occur, they are propagated to RNAs and can become a damaging protein.

The type of therapies that we are developing are termed ASO therapies. ASOs are short single strands of nucleic acids (traditionally thought of as single stranded RNA molecules) which will bind to defective RNA targets in cells and inhibit their ability to be translated into defective proteins. We believe we are a leader in the discovery and development of the class of RNA-targeted ASO drugs called PNAs. Our proprietary PATrOL™ platform allows for a more efficient discovery of drug product candidates, potentially transforming the treatment paradigm for people affected by rare genetic diseases and cancer.

The PATrOL™ platform allows for a potentially more efficient discovery of drug product candidates because of manufacturing consistency and because we are not constrained by folded regions of the target RNA molecule (secondary structures). The peptide backbone of our ASOs is rigid, and once linked together to form a series of backbone subunits, forms a single pre-organized structure. At a more detailed level, each subunit of the peptide backbone has only a single chiral center – a point in the chemical structure where the conformation of the backbone could fluctuate – and this chiral center is locked into one conformation and thus pre-organized to form only a single conformation or stereoisomer. A stereoisomer is a term used in the ASO therapeutics field to mean a string of backbone subunits (usually sugars or modified sugars) with nuclear bases attached that are linked together into a specific sequence that matches (complements) the target sequence, but because of the nature of the backbone subunits used, the drug assumes various conformations often with varying affinity for the target sequence. These stereoisomers often require a manufacturing step to purify the heterogeneous mixture of conformations into a more homogenous mixture or even a single conformation of the drug in order to obtain the hoped-for therapeutic effect. Our PNAs assume only a single conformation with any constellation of nuclear bases added to the backbone or any oligomer length. This backbone also has a neutral charge, as opposed to the negatively charged backbones of DNA and RNA. This neutral charge allows our ASO to open up RNAs which are folded upon themselves and bind to their target sequence. This potentially accelerates identification of drug candidates which have the desired activity.

In addition to the backbone conformational purity which allows for a more efficient discovery of drug product candidates, we also have a kit of proprietary bi-facial or bi-specific nucleotides (traditional nucleotides only have a single binding face and thus are restricted to only binding single-stranded RNA targets) which can be used in any combination to access RNA secondary structures (double stranded RNA targets which are folded upon themselves) such as hairpins. This allows us to potentially access regions of the target transcript which may be unique in secondary structure to allow enhanced selectivity for the target (mutant) RNA vs. the normal RNA. Enhanced selectivity for mutant RNAs vs. normal RNAs is critical as normal RNAs are likely required for effective functioning of the cell. These bi-specific nucleotides can also target genomic loci and microRNAs in their double-stranded form.

In addition to the backbone and modified nuclear bases, the platform toolkit also includes linker technology which, when added to both ends of the PNAs, allow cooperative binding between individual drug molecules once they are engaged with the target RNA to form longer and more tightly bound drugs.

The final component of the platform is a chemical moiety, which is used to decorate the peptide backbone in a proprietary manner and allows the PNAs to penetrate cell membranes and distribute throughout the body when administered systemically.

This relatively simple toolkit of components forms the PATrOL™ platform and allows us to manufacture genome and transcript-specific PNAs quickly for screening.

We are currently focused on therapeutic areas in which we believe our drugs will provide the greatest benefit with a significant market opportunity and intend to utilize our technology to build out a pipeline of custom designed therapeutics for additional high-value disease targets. We are developing several preclinical programs using our PATrOL™ platform, including: NT0100, targeted at HD, a repeat expansion disorder, and NT0200, targeted at myotonic dystrophy ("DM1"). Preclinical studies are being conducted to evaluate the PATrOL™ platform technology and program candidates in the areas of pharmacokinetics and pharmacodynamics, and we expect to report results from those studies beginning in the first calendar quarter of 2020 and in the second calendar quarter of 2020. In addition, the emerging pipeline of other assets that target primary and secondary RNA structure and genomic DNA allows a unique market advantage across a variety of rare diseases and oncology targets.

Using our PATrOL™ platform, we can create ASOs that have distinct potential advantages over other chemical entities currently in the market or in development for gene silencing applications. These advantages include, among others: a backbone that has only one chiral center and thus forms only one stereoisomer; the ability of the PNA backbone to intercalate, open up secondary (RNA folded upon itself) and tertiary structures (RNA molecules that interact with other RNA molecules in the cell) and bind within these double-stranded RNA in a highly selective manner; a proprietary set of engineered nuclear bases that increase selectivity to specific target sequences including secondary and tertiary structures that has been licensed exclusively from CMU; technology to allow self-assembly of our small gamma-PNA at the RNA target to increase selectivity which has been licensed exclusively from CMU; the ability to modulate cell permeability and the ability to pass the blood-brain barrier when administered systemically; the lack of innate or acquired immune responses of similar gamma-PNAs in preclinical models; and potential minimal toxicity based on previous in-vivo studies in rodent models. With these advantages, our PATrOL™ platform-enabled therapies can potentially address a multitude of rare genetic diseases and cancer, among other indications.

Merger

On July 12, 2019, Ohr completed the Merger. At the closing of the Merger, each outstanding share of Legacy NeuBase's capital stock was converted into the right to receive 1.019055643 shares of our common stock. Shares of our common stock commenced trading on the Nasdaq Capital Market under the ticker symbol "NBSE" as of market open on July 15, 2019. Our previous ticker symbol was "OHRP".

Results of Operations

Results of operations for the fiscal year ended September 30, 2019 reflect the following changes from the period from inception (August 28, 2018) to September 30, 2018:

	Period Ended September 30,		
	2019	**2018**	**Change**
General and administrative	$ 9,095,674	$ 28,393	$ 9,067,281
Research and development	4,273,318	12,819	4,260,499
Research and development expense- licenses acquired	12,967,415	-	12,967,415
Total Operating Expenses	26,336,407	41,212	26,295,195
Operating Loss	(26,336,407)	(41,212)	(26,295,195)
Interest expense	(128,951)	(740)	(128,211)
Change in fair value of warrant liabilities	(492,889)	-	(492,889)
Net Loss	$ (26,958,247)	$ (41,952)	$ (26,916,295)

During the fiscal year ended September 30, 2019, we had no revenues and our operating loss increased by $26,295,195 compared to the period from inception to September 30, 2018. Our net loss increased by $26,916,295 for the fiscal year ended September 30, 2019, as compared to the period from inception to September 30, 2018. Until we are able to generate revenues, our management expects to continue to incur net losses.

General and Administrative Expense

General and administrative expense consists primarily of legal and professional fees, wages and stock-based compensation. General and administrative expenses increased by $9,067,281 for the fiscal year ended September 30, 2019, as compared to the period from inception to September 30, 2018, primarily due to an increase in stock-based compensation expense, employee head count and need for legal and professional services.

Research and Development Expense

Research and development expense consist primarily of professional fees, manufacturing expenses, wages and stock-based compensation. Research and development expenses increased by $4,260,499 for the fiscal year ended September 30, 2019, as compared to the period from inception to September 30, 2018, primarily due to an increase in stock-based compensation, employee head count and the ramp up of research and development before and after the close of the Merger with Ohr Pharmaceutical.

Research and Development Expense- licenses acquired

Research and development expense- licenses acquired consists of licenses acquired from CMU and in the Merger with Ohr. Research and development expense- licenses acquired increased by $12,967,415, for the fiscal year ended September 30, 2019, as compared to the period from inception to September 30, 2018, primarily due to our acquisition of license rights in 2019.

Interest Expense

Interest income consists primarily of interest on convertible notes and notes payable. Interest expense increased by $128,211 for the fiscal year ended September 30, 2019, as compared to the period from inception to September 30, 2018, primarily due to the issuance of convertible notes.

Change in fair value of warrant liabilities

Change in fair value of warrant liabilities reflects the changes in warrant liabilities primarily due to changes in our stock price. Change in fair value of warrant liabilities increased by $492,889 for the fiscal year ended September 30, 2019, as compared to the period from inception to September 30, 2018, primarily due to warrants issued in connection with the CMU License Agreement.

Liquidity, Capital Resources and Financial Condition

We have limited working capital reserves with which to fund our continuing operations. We are reliant, at present, upon our capital reserves for ongoing operations and has no revenues.

Net working capital increased from the fiscal year ended September 30, 2018 to the fiscal year ended September 30, 2019 by $8,319,118 (to $8,527,222 from $208,104) primarily due to cash proceeds from financings completed in July 2019. Our quarterly cash burn has increased significantly compared to the prior period from inception to September 30, 2018 due to increased research and development activities and costs associated with the Merger. We anticipate that our cash needs will increase relative to prior periods as we achieve progress with our research and development objectives. Alongside the closing of the Merger, in July 2019, we completed two financings raising gross proceeds of approximately $14 million, and we believe that our current cash balance will provide sufficient capital to continue operations to the end of fiscal 2020. At present, we have no bank line of credit or other fixed source of capital reserves. Should we need additional capital in the future, we will be primarily reliant upon private or public placement of our equity or debt securities, or a strategic transaction, for which there can be no warranty or assurance that we may be successful in such efforts.

Contractual Obligations and Commitments

Leases

From inception through the year ended September 30, 2018, Legacy NeuBase utilized the services of LifeX Labs LLC. These services included accounting consultation and office space rental. This agreement was terminated on January 8, 2019. Dietrich Stephan, our Chief Executive Officer ("CEO"), was on the board and acting as CEO of LifeX Labs LLC until December 28, 2018, when he resigned all positions within LifeX. During the period from August 28, 2018 (inception) to September 30, 2018 and the year ended September 30, 2019, LifeX Labs was paid $1,575 and $10,628, respectively, by Legacy NeuBase.

On March 12, 2019, we entered into a sublease agreement with StartUptown. The monthly rent on the one year sublease is $2,532 and we provided a security deposit of $2,532 upon signature of the agreement. The total sublease liability for the term of the sublease is $30,381 excluding the security deposit. The sublease includes an option to extend the agreement for up to six months. On May 21, 2019, we entered into an amendment to the sublease agreement with StartUptown to increase our office space, whereby the monthly rent on the one year sublease was increased from $2,532 to $4,521 per month. All other material terms remained the same. On July 29, 2019, we entered into a second amendment to the sublease agreement with StartUptown to increase our office space, whereby the monthly rent on the sublease was increased from $4,521 to $6,883 per month. All other material terms remained the same.

Cash Flow Summary

The following table summarizes selected items in our consolidated statements of cash flows:

	For the Year Ended September 30, 2019	For the Period From August 28, 2018 (Inception) to September 30, 2018
Net cash used in operating activities	$ (2,845,488)	$ (455)
Net cash used in investing activities	(685,225)	-
Net cash provided by financing activities	13,595,079	250,055
Net increase in cash and cash equivalents	$ 10,064,366	$ 249,600

Operating Activities from Continuing Operations

Net cash used in operating activities from continuing operations was approximately $2.8 million for the fiscal year ended September 30, 2019 and net cash used in operating activities from continuing operations was approximately $455 for the period from inception to September 30, 2018. Net cash used in operating activities from continuing operations in 2019 was primarily as a result of our net loss, offset by our stock-based compensation expense and research and development expense-licenses acquired.

Investing Activities from Continuing Operations

Net cash used in investing activities from continuing operations was approximately $685 thousand for the fiscal year ended September 30, 2019 and net cash used in investing activities from continuing operations was $0 for the period from inception to September 30, 2018. Net cash used in investing activities in 2019 was primarily as a result of transaction costs paid in connection with the Merger with Ohr and the acquisition of the CMU License as well as the purchase of laboratory and office equipment. These expenditures were partially offset by cash acquired in connection with the Merger with Ohr.

Financing Activities From Continuing Operations

Net cash provided by financing activities was approximately $13.6 million for the fiscal year ended September 30, 2019 and net cash provided by financing activities was approximately $250 thousand for the period from inception to September 30, 2018. Net cash provided by financing activities in 2019 reflects the proceeds from the issuance of common stock in our pre-acquisition and private placement financings. Net cash provided by financing activities in 2019 also reflects the proceeds from the issuance of convertible notes.

Off-Balance Sheet Arrangements

As of September 30, 2019, we did not have any off-balance sheet arrangements as defined in Item 303(a)(4)(ii) of Regulation S-K.

Recent Accounting Pronouncements

In June 2018, the Financial Accounting Standards Board (the "FASB") issued Accounting Standard Update ("ASU") 2018-07, *Compensation- Stock Compensation (Topic 718) Improvements to Nonemployee Share-Based Payment Accounting*, which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The guidance also specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The Company early adopted this standard as of October 1, 2018. The Company did not grant share-based payment awards during the period from August 28, 2018 (inception) through September 30, 2018. Accordingly, the adoption of this standard did not have a material effect on the Company's consolidated financial statements and related disclosures.

In May 2014, the FASB issued ASU 2014-09,*Revenue from Contracts with Customers (Topic 606)*, which requires entities to recognize revenue in a way that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The new guidance also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. The FASB subsequently issued ASU 2016-10, *Revenue from Contracts with Customers: (Topic 606) Identifying Performance Obligations and Licensing*, to address issues arising from implementation of the new revenue recognition standard. The Company adopted the standard using the full retrospective method. The Company does not currently have a revenue stream. Accordingly, the adoption of this standard did not have a material effect on the Company's consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU 2016-2,*Leases*. The new standard establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company plans to adopt this standard on October 1, 2019. The adoption of the standard is not expected to have a material effect on the Company's consolidated financial statements and related disclosures as the Company does not currently have leases with terms longer than 12 months.

Critical Accounting Estimates and Policies

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with United States generally accepted accounting principles ("GAAP"). The preparation of these financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the date of the balance sheet and the reported amounts of expenses during the reporting period. In accordance with GAAP, we evaluate our estimates and judgments on an ongoing basis. The most significant estimates relate to the valuation of share-based compensation, the valuation of licenses, the fair value of warrant liabilities and the valuation allowance of deferred tax assets resulting from net operating losses. We base our estimates and assumptions on current facts, our limited historical experience from operations and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We define our critical accounting policies as those accounting principles that require it to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. While our significant accounting policies are more fully described in Note 2 to our financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe the following are the critical accounting policies used in the preparation of our financial statements that require significant estimates and judgments:

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

We consider all highly-liquid investments purchased with short term maturities to be cash equivalents. We had cash equivalents as of September 30, 2019 and did not have any cash equivalents as of September 30, 2018.

Fair Value of Financial Instruments

In accordance with Accounting Standards Codification ("ASC") 820, the carrying value of cash and cash equivalents, accounts payable and notes payable approximates fair value due to the short-term maturity of these instruments. ASC 820 clarifies the definition of fair value, prescribes methods for measuring fair value, and establishes a fair value hierarchy to classify the inputs used in measuring fair value as follows:

- Level 1 - Quoted prices in active markets for identical assets or liabilities on the reporting date.
- Level 2 - Pricing inputs are based on quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant assumptions are observable in the market or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 - Pricing inputs are generally unobservable and include situations where there is little, if any, market activity for the investment. The inputs into the determination of fair value require management's judgment or estimation of assumptions that market participants would use in pricing the assets or liabilities. The fair values are therefore determined using factors that involve considerable judgment and interpretations, including but not limited to private and public comparables, third-party appraisals, discounted cash flow models and fund manager estimates.

As of September 30, 2019, the fair value of outstanding warrant liabilities measured at fair value on a recurring basis was $496,343. The warrant liabilities are valued using Level 3 valuation inputs. There were no outstanding warrant liabilities as of September 30, 2018.

As of September 30, 2019 and 2018, the recorded values of cash and cash equivalents, accounts payable and the insurance note payable, approximate the fair values due to the short-term nature of the instruments.

Research and Development

Research and development expenses are expensed in the statement of operations as incurred in accordance with the Financial Accounting Standards Board ("FASB") ASC 730, *Research and Development.* Research and development expenses include patent and certain legal fees. We incurred net research and development expenses of $12,819 from inception to September 30, 2018. During the fiscal year ended September 30, 2019, we incurred $4,273,318 in research and development expenses.

Share-Based Compensation

We follow the provisions of ASC 718 – Stock Compensation which requires all share-based payments to employees, including grants of employee stock options, be recognized in the income statement based on their fair values. We have early adopted Accounting Standard Update ("ASU") 2018-07, which expands the scope of ASC 718 to include share based payments granted to nonemployees and supersedes the guidance in ASC 505-50. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model, and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

Stock-based compensation expense is recognized in our financial statements on a straight-line basis over for each separately vesting portion of the award. The stock-based compensation awards generally vest over a period of up to four years. All stock-based compensation costs are recorded in general and administrative or research and development costs in the consolidated statements of operations based upon the underlying individual's role at the Company.

Income taxes

Income taxes are recorded in accordance with Accounting Standards Codification Topic 740,*Income Taxes* ("ASC 740"), which provides for deferred taxes using an asset and liability approach. We recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided, if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

We account for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, we recognize the tax benefit of tax positions to the extent that the benefit would more likely than not be realized assuming examination by the taxing authority. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. NeuBase recognizes any interest and penalties accrued related to unrecognized tax benefits as income tax expense.

The Tax Cuts and Jobs Act (the "Act") was enacted on December 22, 2017. The Act reduces the US federal corporate tax rate from 35% to 21%, and among other changes, eliminates net operating loss carrybacks for losses arising in taxable years beginning after December 31, 2017. Further, operating losses arising in tax years after December 31, 2017, are carried forward indefinitely. The Act did not result in any material changes to our financial statements or results of operations.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Neubase Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Neubase Therapeutics, and Subsidiaries (the Company) as of September 30, 2019 and the related consolidated statements of operations, changes in stockholders' equity (deficit), and cash flows for the year then ended, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of September 30, 2019 and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As further discussed in Note 1 to the accompanying consolidated financial statements, the Company has incurred operating losses since inception, expects to continue to incur significant operating losses for the foreseeable future, and may never become profitable. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

/s/ CohnReznick LLP

We have served as the Company's auditor since 2019.

Roseland, New Jersey
January 10, 2020

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
NeuBase Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of NeuBase Therapeutics, Inc. (the "Company") as of September 30, 2018, and the related consolidated statements of operations, changes in stockholders' equity (deficit), and cash flows for the period from August 28, 2018 (inception) to September 30, 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 as of September 30, 2018, and the results of its operations and its cash flows for the period from August 28, 2018 (inception) to September 30, 2018, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Matter

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether 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 audit 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ MaloneBailey, LLP
www.malonebailey.com
We have served as the Company's auditor from 2018 through 2019.
Houston, Texas
March 7, 2019

NeuBase Therapeutics, Inc. and Subsidiaries
Consolidated Balance Sheets

	September 30,	
	2019	**2018**
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 10,313,966	$ 249,600
Prepaid insurance	449,583	-
Other prepaid expenses and current assets	265,686	1
Total Current Assets	11,029,235	249,601
EQUIPMENT, net	430,995	-
OTHER ASSETS		
Intangible assets, net	145,833	-
Investment	586,418	-
Long-term prepaid insurance	338,916	-
Total Other Assets	1,071,167	-
TOTAL ASSETS	$ 12,531,397	$ 249,601
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable	$ 1,477,152	$ 21,683
Accrued expenses	405,599	19,814
Warrant liabilities	496,343	-
Insurance note payable	122,919	-
Total Current Liabilities	2,502,013	41,497
LONG-TERM LIABILITIES		
Convertible notes payable	-	250,000
Total Long-term Liabilities	-	250,000
TOTAL LIABILITIES	2,502,013	291,497
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY (DEFICIT)		
Preferred stock, $0.0001 par value; 10,000,000 and 6,000,000 shares authorized as of September 30, 2019 and 2018, respectively; no shares issued and outstanding as of September 30, 2019 and 2018	-	-
Common stock, $0.0001 par value; 250,000,000 and 180,000,000 shares authorized as of September 30, 2019 and 2018, respectively; 17,077,873 and 5,727,090 shares issued and outstanding as of September 30, 2019 and 2018, respectively	1,708	573
Additional paid-in capital	37,027,875	(517)
Accumulated deficit	(27,000,199)	(41,952)
Total stockholders' equity (deficit)	10,029,384	(41,896)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 12,531,397	$ 249,601

The accompanying notes are an integral part of these consolidated financial statements.

NeuBase Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Operations

	For the Year Ended September 30, 2019	For the Period From August 28, 2018 (Inception) to September 30, 2018
OPERATING EXPENSES		
General and administrative expenses	$ 9,095,674	$ 28,393
Research and development expenses	4,273,318	12,819
Research and development expense- licenses acquired	12,967,415	-
TOTAL OPERATING EXPENSES	26,336,407	41,212
LOSS FROM OPERATIONS	(26,336,407)	(41,212)
OTHER EXPENSE		
Interest expense	(128,951)	(740)
Change in fair value of warrant liabilities	(492,889)	-
Total other expenses	(621,840)	(740)
NET LOSS	$ (26,958,247)	$ (41,952)
BASIC AND DILUTED LOSS PER SHARE	$ (3.26)	$ (0.01)
WEIGHTED AVERAGE SHARES OUTSTANDING:		
BASIC AND DILUTED	8,271,707	5,727,090

The accompanying notes are an integral part of these consolidated financial statements.

NeuBase Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Cash Flows

	For the Year Ended September 30, 2019	For the Period From August 28, 2018 (Inception) to September 30, 2018
Cash flows from operating activities:		
Net loss	$ (26,958,247)	$ (41,952)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation	9,785,083	-
Research and development expense - license acquired- CMU	1,046,965	-
Research and development expense - license acquired- Ohr	11,920,450	-
Change in fair value of warrant liabilities	492,889	-
Depreciation and amortization	128,372	-
Non-cash amortization on convertible notes discount	94,444	-
Non-cash interest expense on convertible notes	21,772	-
Changes in operating assets and liabilities (excluding the effects of acquisition)		
Prepaid expenses and other current assets	(386,499)	-
Accounts payable	962,434	21,683
Accrued expenses	385,765	19,814
Long term prepaid insurance expense	(338,916)	-
Net cash used in operating activities	(2,845,488)	(455)
Cash flows from investing activities		
Purchase of laboratory and office equipment	(455,200)	-
Cash acquired in connection with Acquisition of Ohr	752,419	-
Payment of transaction costs for Acquisition of Ohr	(884,981)	-
Payment of transaction costs for licenses acquired- CMU	(43,463)	-
Cash paid for license acquired- CMU	(54,000)	-
Net cash used in investing activities	(685,225)	-
Cash flows from financing activities		
Proceeds from issuance of common stock in pre-acquisition financing, net of issuance costs	8,268,157	55
Proceeds from issuance of common stock in private placement financing, net of issuance costs	4,957,397	-
Proceeds from issuance of convertible notes	600,000	250,000
Payment for warrant redemption	(141,864)	-
Principal payment of financed insurance	(90,081)	-
Proceeds from issuance of common shares for services	1,474	-
Proceeds from prefunded warrant	10	-
Repurchase of common stock	(14)	-
Net cash provided by financing activities	13,595,079	250,055
Net increase in cash and cash equivalents	10,064,366	249,600
Cash and cash equivalents, beginning of period	249,600	-
Cash and cash equivalents, end of period	**$ 10,313,966**	**$ 249,600**
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 3,177	$ -
Cash paid for income taxes	$ -	$ -
Non-cash investing and financing activities:		
Issuance of common stock for research and development expense-licenses acquired - CMU	$ 844,600	$ -
Issuance of common stock for conversion of debt	$ 944,444	$ -
Issuance of common stock for conversion of accrued interest	$ 21,772	$ -
Issuance of common stock for the cashless exercise of warrant	$ 429,677	$ -
Insurance financed through note payable	$ 213,000	$ -
Issuance of common stock and options for acquisition of Ohr	$ 11,776,927	$ -
Unpaid stock subscription	$ -	$ 1

The accompanying notes are an integral part of these consolidated financial statements.

NeuBase Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Changes in Stockholders' Equity (Deficit)

	Treasury Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance as of August 28, 2018 (Inception)	**-**	**$ -**	**-**	**$ -**	**$ -**	**$ -**	**$ -**
Common stock issued for cash	-	-	5,727,090	573	(517)	-	56
Net loss	-	-	-	-	-	(41,952)	(41,952)
Balance as of September 30, 2018	**-**	**-**	**5,727,090**	**573**	**(517)**	**(41,952)**	**(41,896)**
Stock-based compensation expense	-	-	-	-	9,785,083	-	9,785,083
Repurchase of common stock	(1,401,202)	(140)	-	-	126	-	(14)
Retirement of common stock	1,401,202	140	(1,401,202)	(140)	-	-	-
Issuance of common stock for research and development expense- license acquired - CMU	-	-	835,625	84	844,516	-	844,600
Issuance of restricted stock for services	-	-	1,532,984	153	1,321	-	1,474
Cash received for prefunded warrants	-	-	-	-	10	-	10
Issuance of common stock for conversion of notes payable and accrued interest	-	-	609,874	61	966,155	-	966,216
Issuance of common stock for the cashless exercise of warrants	-	-	103,787	10	429,667	-	429,677
Issuance of common stock in pre-acquisition private placement, net of issuance costs	-	-	5,302,005	530	8,267,627	-	8,268,157
Issuance of common stock and options for acquisition of Ohr	-	-	2,829,248	283	11,776,644	-	11,776,927
Issuance of common stock in a private placement financing, net of issuance costs	-	-	1,538,462	154	4,957,243	-	4,957,397
Net loss	-	-	-	-	-	(26,958,247)	(26,958,247)
Balance as of September 30, 2019	**-**	**$ -**	**17,077,873**	**$ 1,708**	**$ 37,027,875**	**$ (27,000,199)**	**$ 10,029,384**

The accompanying notes are an integral part of these consolidated financial statements.

1. Organization and Description of Business

NeuBase Therapeutics, Inc. and subsidiaries (the "Company" or "NeuBase") is developing a modular peptide-nucleic acid antisense oligonucleotide ("PATrOL™") platform to address genetic diseases caused by mutant proteins, with a single, cohesive approach. The systemically-deliverable PATrOL™ therapies are designed to improve upon current gene silencing treatments by combining the advantages of synthetic approaches with the precision of antisense technologies. NeuBase plans to use its platform to address genetic diseases, with an initial focus on Huntington's Disease ("HD") and Myotonic Dystrophy ("DM1"), as well as other genetic disorders.

NeuBase is a pre-clinical-stage biopharmaceutical company and continues to develop its clinical and regulatory strategy with its internal research and development team with a view toward prioritizing market introduction as quickly as possible. NeuBase's lead programs are NT0100 and NT0200.

NT0100 is a PATrOL™-enabled therapeutic program being developed for systemic administration to target the mutant expansion in the HD messenger ribonucleic acid ("RNA"). NT0100 falls into the category of peptide nucleic acids ("PNAs") which has the potential to be highly selective for the mutant transcript vs. the wild-type transcribed allele and hold the promise to be effective for all HD patients. PATrOL™-enabled drugs also have the unique ability to open RNA secondary structures and bind to either the primary nucleotide sequences or the secondary and/or tertiary structures. NeuBase believes the NT0100 program addresses an unmet need for a disease which current has no effective therapeutics that target the core etiology of the condition. NeuBase believes there is a large opportunity in the U.S. and European markets for drugs in this space.

NT0200 is a PATrOL™-enabled therapeutic program being developed for systemic administration to target the mutant expansion in the DM1 disease mRNA. NT0200 falls into the category of PNAs which has the potential to be highly selective for the mutant transcript versus the wild-type transcribed allele and promises to be effective for all DM1 patients as it directly targets the expansion itself. NeuBase believes the NT0200 program addresses an unmet need for a disease which current has no effective therapeutics that target the core etiology of the condition. NeuBase believes there is also a large opportunity in the U.S. and European markets for drugs in this space.

Acquisition of Ohr Pharmaceutical, Inc. and Reverse Stock Split

On July 12, 2019, the Company (formerly known as Ohr Pharmaceutical, Inc. ("Ohr")) completed a reverse acquisition transaction in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of January 2, 2019, by and among the Company, Ohr Acquisition Corp. ("Merger Sub"), and NeuBase Therapeutics, Inc. ("Private NeuBase"), as amended by the First Amendment thereto made and entered into as of June 27, 2019 (as amended, the "Acquisition Agreement"), pursuant to which Merger Sub merged with and into Private NeuBase, with Private NeuBase ("renamed as NeuBase Corporation") surviving as a wholly owned subsidiary of the Company (the "Ohr Acquisition"). On July 12, 2019, immediately after completion of the Ohr Acquisition, the Company changed its name to "NeuBase Therapeutics, Inc."

Under the terms of the Acquisition Agreement, the Company issued shares of common stock to Private NeuBase's stockholders at an exchange rate of 1.019055643 shares of common stock for each share of Private NeuBase's common stock outstanding immediately prior to the Ohr Acquisition (the "Exchange Ratio"). The Company also assumed all of the stock options outstanding and unexercised under the NeuBase Therapeutics, Inc. 2018 Equity Incentive Plan with such stock options henceforth representing the right to purchase a number of shares of common stock equal to the Exchange Ratio multiplied by the number of shares of Private NeuBase's common stock previously represented by such options (and rounding the resulting number down to the nearest whole share) at an exercise price equal to the previous per share exercise price of such options divided by the Exchange Ratio (and rounding the resulting number up to the nearest whole cent).

Immediately after the Ohr Acquisition, there were 15,524,219 shares of common stock outstanding. Immediately after the Ohr Acquisition, the former stockholders, optionholders, warrantholders and noteholders of Private NeuBase owned, or held rights to acquire, approximately 85% of the fully-diluted common stock of the combined company, with the Company's stockholders, optionholders and warrantholders immediately prior to the Ohr Acquisition owning, or holding rights to acquire, approximately 15% of the fully-diluted common stock of the combined company.

The Ohr Acquisition was accounted for as a "reverse asset acquisition", whereby Private NeuBase was determined to be the accounting acquirer based upon the terms of the Ohr Acquisition and other factors including: (i) Private NeuBase stockholders and other persons holding securities convertible, exercisable or exchangeable directly or indirectly for Private NeuBase common stock owned approximately 85% of the Company immediately following the effective time of the Ohr Acquisition, (ii) Private NeuBase holds all (five) board seats of the combined company and (iii) Private NeuBase' management holds key positions in the management of the combined company. The historical financial statements, outstanding shares and all other historical share information have been adjusted by multiplying the respective share amount by the Exchange Ratio as if the Exchange Ratio had been in effect for all periods presented.

Prior to the Ohr Acquisition, on January 18, 2019, following a special meeting of the Company's stockholders, the board of directors of the Company approved a one-for-twenty reverse stock split of the Company's issued and outstanding shares of common stock (the "Reverse Stock Split"). On January 23, 2019, the Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment to its Certificate of Incorporation to effect the Reverse Stock Split. The Company's common stock began trading on a split-adjusted basis when the market opened on February 4, 2019.

Liquidity

The Company had no revenues, incurred operating losses since inception, and expects to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of September 30, 2019, the Company had $10,313,966 in cash and an accumulated deficit of $27,000,199. The Company has funded its operations through the issuance of convertible notes (see Note 5), sale of common stock (see Note 6) and warrants (see Note 6).

The accompanying consolidated financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to its ability to continue as a going concern.

The Company's future liquidity and capital funding requirements will depend on numerous factors, including:

- its ability to raise additional funds to finance its operations;
- its ability to maintain compliance with the listing requirements of The Nasdaq Capital Market ("Nasdaq");
- the outcome, costs and timing of clinical trial results for the Company's current or future product candidates;
- the extent and amount of any indemnification claims;
- litigation expenses and the extent and amount of any indemnification claims;
- the emergence and effect of competing or complementary products;
- its ability to maintain, expand and defend the scope of its intellectual property portfolio, including the amount and timing of any payments the Company may be required to make, or that it may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- its ability to retain its current employees and the need and ability to hire additional management and scientific and medical personnel;
- the terms and timing of any collaborative, licensing or other arrangements that it has or may establish;
- the trading price of its common stock; and
- its ability to increase the number of authorized shares outstanding to facilitate future financing events.

The Company will likely need to raise substantial additional funds through one or more of the following: issuance of additional debt or equity, or the completion of a licensing transaction for one or more of the Company's pipeline assets. If the Company is unable to maintain sufficient financial resources, its business, financial condition and results of operations will be materially and adversely affected. This could affect future development and business activities and potential future clinical studies and/or other future ventures. Failure to obtain additional equity or debt financing will have a material, adverse impact on the Company's business operations. There can be no assurance that the Company will be able to obtain the needed financing on acceptable terms or at all. Additionally, equity or debt financings will likely have a dilutive effect on the holdings of the Company's existing stockholders. Accordingly, there are material risks and uncertainties that raise substantial doubt about the Company's ability to continue as a going concern.

2. Significant Accounting Policies

Basis of Presentation

The Company's consolidated financial statements been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated during the consolidation process. The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. The most significant estimates in the Company's consolidated financial statements relate to the valuation of share-based compensation, the valuation of licenses, the fair value of warrant liabilities and the valuation allowance of deferred tax assets resulting from net operating losses. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to credit risk consist principally of cash and cash equivalents. Cash and cash equivalents are maintained in accounts with financial institutions, which, at times may exceed the Federal depository insurance coverage of $250,000. The Company has not experienced losses on these accounts and management believes, based upon the quality of the financial institutions, that the credit risk with regard to these deposits is not significant.

Fair Value Measurements

Fair value measurements are based on the premise that fair value is an exit price representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the following three-tier fair value hierarchy has been used in determining the inputs used in measuring fair value:

Level 1- Quoted prices in active markets for identical assets or liabilities on the reporting date.

Level 2- Pricing inputs are based on quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant assumptions are observable in the market or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3- Pricing inputs are generally unobservable and include situations where there is little, if any, market activity for the investment. The inputs into the determination of fair value require management's judgment or estimation of assumptions that market participants would use in pricing the assets or liabilities. The fair values are therefore determined using factors that involve considerable judgment and interpretations, including but not limited to private and public comparables, third-party appraisals, discounted cash flow models and fund manager estimates.

Financial instruments measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. Management's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset or liability. The use of different assumptions and/or estimation methodologies may have a material effect on estimated fair values. Accordingly, the fair value estimates disclosed or initial amounts recorded may not be indicative of the amount that the Company or holders of the instruments could realize in a current market exchange.

The following table presents the Company's fair value hierarchy for its warrant liabilities measured at fair value on a recurring basis at September 30, 2019:

	Fair Value Measurements as of September 30, 2019			
	(Level 1)	(Level 2)	(Level 3)	Total
Liabilities				
Warrant liabilities	$ -	-	496,343	$ 496,343

The fair value of the warrant liabilities were determined using the Black-Scholes option pricing model. The following assumptions were used in determining the fair value of the warrant liabilities as of September 30, 2019:

	Year ended September 30, 2019
Expected common stock price volatility	76.6% - 78.4%
Risk-free interest rate	1.6% - 1.63%
Expected term (years)	2.2 - 2.5
Expected dividend yield	-

The change in fair value of the warrant liabilities for the year ended September 30, 2019 is as follows:

	Warrant liabilities
Fair value as of September 30, 2018	$ -
Warrants issued in connection with license acquired- CMU	104,902
Warrants assumed in connection with acquisition of Ohr	470,093
Extinguishment of warrant liability related to the cashless exercise of warrants	(429,677)
Extinguishment of warrant liability related to warrants redeemed for cash	(141,864)
Change in fair value	492,889
Fair value as of September 30, 2019	$ 496,343

As of September 30, 2019 and 2018, the recorded values of cash and cash equivalents, accounts payable and the insurance note payable, approximate the fair values due to the short-term nature of the instruments.

Equipment

Equipment is stated at cost less accumulated depreciation. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets. The Company estimates useful lives as follows:

- Laboratory equipment: five years
- Office equipment: three years

Intangible Assets

Identifiable intangible assets includes clinical trial data acquired in the Ohr Acquisition and is being amortized over its estimated useful life (approximately six months), which approximates the pattern in which the assets' economic benefits are consumed. The fair value of the intangible asset was determined using recent and potential market transactions which are management's best estimates of inputs and assumptions that a market participant would use. The estimates are based on assumptions that the Company believes to be reasonable, but such assumptions are subject to unpredictability and uncertainty.

For amortizable intangible assets, the Company performs an impairment analysis when circumstances suggest that the carrying values of those assets may not be recoverable. Recoverability of an asset to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted cash flows expected to be generated by the asset. If such asset is considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the asset exceeds its fair value. There were no indicators of impairments for the year ended September 30, 2019.

Impairment of Long-Lived Assets

The Company reviews the carrying value of equipment for indicators of possible impairment whenever events and circumstances indicate that the carrying value of an asset or asset group may not be recoverable from the estimated future net undiscounted cash flows expected to result from its use and eventual disposition. In cases where estimated future net undiscounted cash flows are less than the carrying value, an impairment loss is recognized equal to an amount by which the carrying value exceeds the fair value of the asset or asset group. The factors that would be considered by management in performing this assessment include current operating results, trends and prospects, the manner in which the property is used and the effects of obsolescence, demand, competition and other economic factors. Based on this assessment, there was no impairment at September 30, 2019.

Leases

Leases are reviewed and classified as capital or operating at their inception. The Company records rent expense associated with its operating lease on a straight-line basis over the term of the lease.

Research and Development

The Company expenses research and development costs as operating expenses as incurred. Research and development expenses consist primarily of:

- salaries and related benefits for personnel in research and development functions, including stock-based compensation and benefits;
- fees paid to consultants and laboratory work and statistical compilation and analysis;
- allocation of facility lease and maintenance costs;
- depreciation of laboratory equipment and computers;
- costs related to purchasing raw materials for and producing our product candidates for potential clinical trials;
- costs related to compliance with regulatory requirements; and
- license fees related to in-licensed technologies.

Research and Development Expense- Licenses Acquired

The Company evaluates whether acquired intangible assets are a business under applicable accounting standards. Additionally, the Company evaluates whether the acquired assets have an alternative future use. Intangible assets that do not have alternative future use are considered acquired in-process research and development. When the acquired in-process research and development assets are not part of a business combination, the value of the consideration paid is expensed on the acquisition date. Future costs to develop these assets are recorded to research and development expense as they are incurred.

Stock-Based Compensation

The Company expenses stock-based compensation to employees, non-employees and board members over the requisite service period based on the estimated grant-date fair value of the awards and actual forfeitures. The Company accounts for forfeitures as they occur. Stock-based awards with graded-vesting schedules are recognized on a straight-line basis over the requisite service period for each separately vesting portion of the award. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model, and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. All stock-based compensation costs are recorded in general and administrative or research and development costs in the consolidated statements of operations based upon the underlying individual's role at the Company.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred income taxes are recorded for temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities. Deferred tax assets and liabilities reflect the tax rates expected to be in effect for the years in which the differences are expected to reverse. A valuation allowance is provided if it is more-likely than not that some or all of the deferred tax assets will not be realized.

The Company also follows the provisions of accounting for uncertainty in income taxes which prescribes a model for the recognition and measurement of a tax position taken or expected to be taken in a tax return, and provides guidance on derecognition, classification, interest and penalties, disclosure and transition. In accordance with this guidance, tax positions must meet a more-likely than not recognition threshold and measurement attribute for the financial statement recognition and measurement of tax position.

The Company's policy is to account for income tax related interest and penalties in income tax expense in the accompanying consolidated statements of operations.

Recent Accounting Pronouncements

In June 2018, the Financial Accounting Standards Board (the "FASB") issued Accounting Standard Update ("ASU") 2018-07, *Compensation- Stock Compensation (Topic 718) Improvements to Nonemployee Share-Based Payment Accounting*, which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The guidance also specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The Company early adopted this standard as of October 1, 2018. The Company did not grant share-based payment awards during the period from August 28, 2018 (inception) through September 30, 2018. Accordingly, the adoption of this standard did not have a material effect on the Company's consolidated financial statements and related disclosures.

In May 2014, the FASB issued ASU 2014-09,*Revenue from Contracts with Customers (Topic 606)*, which requires entities to recognize revenue in a way that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The new guidance also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. The FASB subsequently issued ASU 2016-10, *Revenue from Contracts with Customers: (Topic 606) Identifying Performance Obligations and Licensing*, to address issues arising from implementation of the new revenue recognition standard. The Company adopted the standard using the full retrospective method. The Company does not currently have a revenue stream. Accordingly, the adoption of this standard did not have a material effect on the Company's consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU 2016-2,*Leases*. The new standard establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company plans to adopt this standard on October 1, 2019. The adoption of the standard is not expected to have a material effect on the Company's consolidated financial statements and related disclosures as the Company does not currently have leases with terms longer than 12 months.

3. Acquisition of Ohr Pharmaceutical, Inc.

As described in Note 1, on July 12, 2019, the Company completed the acquisition of Ohr in accordance with the terms of the Acquisition Agreement. The acquisition was accounted for as a reverse asset acquisition.

Pursuant to the Acquisition Agreement, the Company issued to Private NeuBase stockholders, optionholders, warrantholders and noteholders of Private NeuBase a number of shares of Ohr common stock representing approximately 85% of the fully diluted common stock of Ohr. The cost of the Ohr acquisiton, which represents the consideration transferred to Ohr's stockholders in the Ohr Acquisition, was calculated based on the fair value of common stock of the combined company that Ohr stockholders own as of the closing of the Ohr Acquisition on July 12, 2019. With no active trading market for shares of Private NeuBase common stock, fair value of the Ohr common stock represents a more reliable measure of the fair value of consideration transferred in the acquisition. The cost of the Ohr acquisiton of $12.7 million consists of the following:

Number of shares of the combined company to be owned by Ohr security holders	2,829,248
Fair value per share of Ohr common stock as of July 11, 2019	$ 4.14
Fair value of Ohr shares outstanding	11,713,087
Fair value of options assumed	63,840
Fair value of common stock and options issued	11,776,927
Transaction costs	884,981
Total cost of the Ohr acquisiton	$ 12,661,908

The total cost of the Ohr Acquisition was allocated to the net assets acquired as follows:

Cash and cash equivalents	$ 752,419
Prepaid expenses and other current assets	115,769
Investment in DepYmed	586,418
Intangible assets	250,000
Warrant liability	(470,093)
Accounts payable and accrued expenses	(493,055)
Fair value of net assets acquired	741,458
Research and development expense- License acquired	11,920,450
Total cost of Ohr Acquisition	$ 12,661,908

The Company identified an intangible asset related to Ohr's clinical trial data with an estimated fair value of $250,000. This intangible asset is being amortized on a straight-line basis over its estimated useful life of six months.

As of the asset acquisition date, Ohr's SKS sustained release ocular drug delivery platform technology ("SKS Technology") acquired had not yet attained regulatory approval. Accordingly, this intangible asset represents an in-process research and development asset with no future alternative use and was immediately expensed under the guidance of Accounting Standard Codification ("ASC") 730, *Research and Development*, upon the asset acquisition.

4. License Agreement with Carnegie Mellon University

On December 17, 2018, Private NeuBase entered into a License Agreement with Carnegie Mellon University (the "CMU License Agreement"). Under the CMU License Agreement, Carnegie Mellon University ("CMU") granted Private NeuBase an exclusive, worldwide right to the PATrOL™ technology, with patents and patent applications describing composition of matter and uses of the platform.

As partial consideration for the license right, Private NeuBase issued and delivered to CMU 820,000 shares of Private NeuBase common stock (or 835,625 shares of common stock of the Company converted at the Exchange Ratio provided for in the Acquisition Agreement), which constituted 8.2% of the then fully-diluted capitalization of Private NeuBase. Further, as partial consideration for the license right, Private NeuBase issued a warrant to CMU, exercisable only upon the earlier of (i) the day that Private NeuBase receives cumulative capital funding or revenues equal to $2 million or (ii) 30 days prior to any change of control event that provides for the issuance of shares, for a number of shares of Private NeuBase common stock sufficient such that when added to the 820,000 shares of Private NeuBase common stock, CMU holds in the aggregate an amount equal to 8.2% of the fully-diluted capitalization of Private NeuBase; provided, however, that for purposes of calculating 8.2%, only the first $2 million of capital funding shall be considered in the determination of Private NeuBase's fully-diluted capitalization. Under the CMU License Agreement, CMU has preemptive rights with respect to certain future sales of securities by Private NeuBase for capital-raising purposes, "piggyback" registration rights and co-sale rights with respect to certain resales of shares of Private NeuBase by Private NeuBase's stockholders.

Pursuant to the CMU License Agreement, Private NeuBase must achieve certain milestones to demonstrate certain developments of the licensed product. Private NeuBase may obtain one six-month extension to meet each milestone with a nominal payment to CMU. Further, subject to certain conditions, Private NeuBase will pay to CMU royalties at a percentage of net sales in the low single digits and sublicensing fees.

The Company recognized research and development expense totaling approximately $1,046,965 during the year ended September 30, 2019 for the value of consideration paid in connection with the license agreement. The consideration paid for the license right is as follows:

Cash consideration	$	54,000
Acquisition costs		43,463
Fair value of common stock		844,600
Fair value of warrant liability issued		104,902
Total consideration	$	1,046,965

5. Notes Payable

From September 2018 to February 2019, the Company entered into convertible note agreements with investors. The aggregate principal amount of the convertible notes was $850,000 and were due one to two years from issuance, no later February 2021, with simple interest at the rate of 6% per annum.

The outstanding principal and accrued interest of each note automatically converted into shares of Private NeuBase common stock, upon the issuance of Private NeuBase common stock in connection with the pre-acquisition financing, by dividing the then-outstanding balance of each convertible note by 90% of the purchase price per share paid by investors in the pre- acquisition financing, or $1.6145. In connection with the closing of the pre-acquisition financing, the convertible notes plus unpaid interest were converted into 598,472 shares of Private NeuBase common stock at a price of $1.6145 per share. Upon the consummation of the Ohr Acquisition, the convertible note shares were converted pursuant to the Exchange Ratio in the Acquisition Agreement into the right to receive 609,874 shares of common stock.

During the year ended September 30, 2019, the Company recognized cumulative interest expense of $124,000, which includes approximately $94,000 related to the amortization of the discount on the convertible note agreements.

During the year ended September 30, 2019, the Company entered into short-term notes payable for an aggregate of $213,000, bearing interest at 5.75% per year to finance certain insurance policies. Principal and interest payments related to these notes are being be repaid over a 10-month period with the final payment due on February 28, 2020. As of September 30, 2019, the Company's insurance note payable balance was approximately $123,000.

6. Stockholders' Equity

Preferred Stock

The Company is authorized to issue 10 million shares of preferred stock, par value $0.0001 as of September 30, 2019 and had 6 million authorized shares of preferred stock as of September 30, 2018. No shares of preferred stock were issued or outstanding as of September 30, 2019 or 2018.

Common Stock

The Company has authorized 250 million shares of common stock, $0.0001 par value per share as of September 30, 2019 and had authorized 180 million shares of common stock, $0.0001 par value per share, as of September 30, 2018. Each share of common stock is entitled to one voting right. Common stock owners are entitled to dividends when funds are legally available and declared by the Company's board of directors.

Pre-Acquisition Financing

On July 11, 2019, Private NeuBase closed a private placement transaction, whereby, among other things, Private NeuBase issued to certain investors shares of Private NeuBase common stock immediately prior to the Ohr Acquisition in a private placement transaction (the "Pre-Acquisition Financing").

At the closing of the Pre-Acquisition Financing, Private NeuBase issued and sold to the Pre-Acquisition Financing investors an aggregate of 5,202,879 shares of Private NeuBase's common stock, resulting in approximately $8.3 million net of issuance costs. Upon the consummation of the Ohr Acquisition, the Pre-Acquisition Financing shares were converted pursuant to the Exchange Ratio in the Acquisition Agreement into the right to receive 5,302,005 shares of common stock.

Post-Acquisition Private Placement

On July 12, 2019, the Company entered into a Common Stock Purchase Agreement (the "Purchase Agreement") with certain accredited investors for the sale by the Company in a private placement (the "Private Placement") of an aggregate 1,538,462 shares of common stock, at a purchase price of $3.25 per share. The closing of the Private Placement occurred on July 15, 2019. The aggregate net proceeds from the sale of the common stock was approximately $5.0 million.

Convertible Notes

As described in Note 5, in connection with the closing of the Pre-Acquisition Financing, the convertible notes plus unpaid interest, of approximately $966,216 were converted into 598,472 shares of Private NeuBase common stock at a price of $1.6145 per share. Upon the consummation of the Ohr Acquisition, the convertible note shares were converted pursuant to the Exchange Ratio in the Acquisition Agreement into the right to receive 609,874 shares of common stock.

Asset Acquisitions

As described in Note 4, in connection with the acquisition of the CMU License Agreement, Private NeuBase issued 820,000 shares of Private NeuBase common stock. Upon the consummation of the Ohr Acquisition, the shares issued in connection with the CMU License Agreement were converted pursuant to the Exchange Ratio in the Acquisition Agreement into the right to receive 835,625 shares of common stock.

As described in Note 3, in connection with the acquisition of Ohr, the Company issued to Private NeuBase stockholders, optionholders, warrantholders and noteholders of NeuBase a number of shares of Ohr common stock at the exchange rate of 1.019055643 shares of common stock for each share of Private NeuBase's common stock outstanding immediately prior to the Ohr Acquisition. The common stock of the combined company that Ohr stockholders owned as of the closing of the Ohr Acquisition on July 12, 2019 is 2,829,248 shares of common stock.

Treasury Stock

At September 30, 2018, Private NeuBase had sold 5,620,000 shares of Private NeuBase common stock (or 5,727,090 shares of common stock of the Company converted at the Exchange Ratio provided for in the Acquisition Agreement) to Private NeuBase's founders and other employees and service providers for gross proceeds of $55. The Private NeuBase common stock issued to the Company's employees was eligible to be repurchased by the Company for a 36 month period following the sale, subject to the amount available for repurchase, in the event the purchaser is no longer providing services to the Company. The Company's repurchase of eligible shares was to be at a price per share equal to the lesser of (i) the fair market value of the shares at the time the repurchase option is exercised, as determined by the Company's board of directors, and (ii) the original purchase price. The Company was able to exercise its repurchase option as to any or all of the shares available for repurchase at any time after the restricted stock purchaser ceases to provide services to Private NeuBase. During the year ended September 30, 2019, the Company repurchased 1,375,000 shares of Private NeuBase common stock (or 1,401,202 shares of common stock of the Company converted at the Exchange Ratio provided for in the Acquisition Agreement) for $14. During the year ended September 30, 2019, the Company retired the 1,375,000 shares of Private NeuBase common stock (or 1,401,202 shares of common stock of the Company converted at the Exchange Ratio provided for in the Acquisition Agreement).

Warrants

Below is a summary of the Company's issued and outstanding warrants as of September 30, 2019:

Expiration date	Exercise Price	Warrants Outstanding
December 13, 2021	$ 55.00	20,627
April 10, 2022	20.00	695,312
October 31, 2019	20.00	12,500
		728,439

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)
Outstanding as of September 30, 2018	-	$ -	-
Assumed in connection with acquisition of Ohr	804,940	24.22	2.67
Issued in connection with license acquired- CMU	103,787		
Exercised	(103,787)		
Redeemed	(76,501)	55.00	2.43
Outstanding as of September 30, 2019	728,439	$ 20.99	2.48
Exercisable as of September 30, 2019	728,439	$ 20.99	2.48

In connection with the Ohr Acquisition described in Note 1, the Company assumed outstanding warrants issued by Ohr and were measured at fair value. The Company determined 792,440 of the warrants assumed from Ohr should be accounted for as a liability in accordance with the guidance in ASC 815, *Derivatives and Hedging*. The subsequent changes in the fair value of the derivative warrants are recorded in earnings each reporting period. The Company determined 12,500 warrants assumed from Ohr met the scope exception in ASC 815 and are therefore classified as equity. Subsequent changes in fair value are not recognized as long as the contract continues to be classified in equity.

During the year ended September 30, 2019, 76,501 warrants acquired from Ohr were redeemed for cash of approximately $142,000.

In connection with the acquisition described in Note 3, the Company issued a warrant, exercisable only upon the occurrence of certain events, for a number of shares of Private NeuBase common stock sufficient such that when added to the 820,000 shares of Private NeuBase common stock issued to CMU, CMU would hold in the aggregate an amount equal to 8.2% of the fully-diluted shares of the Private NeuBase's common stock; provided, however, that for the purpose of calculating the 8.2%, only the first $2 million in funding shall be considered (the "CMU Warrant"). The CMU Warrant had an aggregate exercise price of $10.00, was exercisable upon the earlier of the (i) the day that the Company's cumulative capital funding and/or receipt of cumulative revenue equals the sum of $2.0 million or (ii) 30 days prior to any Qualified Sale (as defined in the CMU License Agreement) or any other merger, consolidation, reorganization, combination or similar transaction in which the Owners of the Company immediately before such transaction do not continue to control at least a majority of the voting interests in the Company after such transaction. The CMU Warrants became exercisable upon the Pre-Acquisition Financing and the CMU Warrant was exercised for 101,847 shares of Private NeuBase common stock (the "CMU Warrant Shares"). Upon the consummation of the Ohr Acquisition, the CMU Warrant Shares were converted pursuant to the Exchange Ratio in the Acquisition Agreement into 103,787 shares of common stock.

7. Net Loss Per Common Share

Basic net loss per share is computed by dividing net loss applicable to common stockholders by the weighted average number of shares of common stock outstanding during each period. Diluted net loss per share includes the effect, if any, from the potential exercise or conversion of securities, such as convertible debt, warrants and stock options that would result in the issuance of incremental shares of common stock. In computing the basic and diluted net loss per share applicable to common stockholders, the weighted average number of shares remains the same for both calculations due to the fact that when a net loss exists, dilutive shares are not included in the calculation as the impact is anti-dilutive.

The following potentially dilutive securities outstanding for the year ended September 30, 2019 and for the period from August 28, 2018 (inception) to September 30, 2018 have been excluded from the computation of diluted weighted average shares outstanding, as they would be anti-dilutive:

	As of September 30	
	2019	2018
Outstanding stock options	6,375,966	-
Unvested restricted stock	6,875	-
Outstanding warrants	728,439	-
Convertible notes	-	218,723
	7,111,280	218,723

8. Stock-Based Compensation

The Company has a 2016 Consolidated Stock Incentive Plan (the "2016 Plan") and a 2019 Stock Incentive Plan (the "2019 Plan"), which provide for the issuance of incentive and non-incentive stock options, restricted and unrestricted stock awards, stock unit awards and stock appreciation rights. Options and restricted stock units granted generally vest over a period of one to four years and have a maximum term of ten years from the date of grant. Upon completion of the Ohr Acquisition, the Company assumed the awards outstanding under the NeuBase Therapeutics, Inc. 2018 Equity Incentive Plan.

As of September 30, 2019, an aggregate of 3,100,000 shares of common stock were authorized under the 2019 Plan, subject to an "evergreen" provision that will automatically increase the maximum number of shares of Common Stock that may be issued under the term of the 2019 Plan. As of September 30, 2019, 152,248 common shares were available for future grants under the 2019 Plan. As of September 30, 2019, 291,667 shares of common stock were authorized under the 2016 Plan and 147,041 common shares were available for future grants under the 2016 Plan.

Stock Options

Below is a table summarizing the options issued and outstanding as of and for the year ended September 30, 2019:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Total Aggregate Intrinsic Value
Outstanding as of September 30, 2018	-	$ -	-	-
Assumed in connection with license acquired- Ohr	106,000	13.31		
Granted	6,269,966	2.52		
Outstanding at September 30, 2019	6,375,966	$ 2.70	9.4	$ 16,650,319
Exercisable as of September 30, 2019	4,117,187	$ 1.23	9.2	$ 16,650,319

As of September 30, 2019, the unrecognized compensation costs of $7.1 million will be recognized over an estimated weighted-average amortization period of 1.7 years. During the year ended September 30, 2019, no stock options were exercised or forfeited.

The fair value of stock option grants are estimated on the date of grant using the Black-Scholes option-pricing model. The Company was historically a private company and lacked company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies. Additionally, due to an insufficient history with respect to stock option activity and post-vesting cancellations, the expected term assumption for employee grants is based on a permitted simplified method, which is based on the vesting period and contractual term for each tranche of awards. The mid-point between the weighted-average vesting term and the expiration date is used as the expected term under this method. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect for time periods approximately equal to the expected term of the award. Expected dividend yield is zero based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The weighted average grant date fair value of options granted during the year ended September 30, 2019 was $2.31.

Key assumptions used to estimate the fair value of the stock options granted during the year ended September 30, 2019 included:

	Year ended September 30, 2019
Expected common stock price volatility	75.6% - 78.4%
Risk-free interest rate	1.8% - 2.5%
Expected term of options (years)	1.6 - 7
Expected dividend yield	-

Restricted Stock

A summary of the changes in the outstanding restricted stock during the year ended September 30, 2019 is as follows:

	Unvested Restricted Stock	Weighted Grant Date Fair Value Price
Outstanding as of September 30, 2018	-	$ -
Granted	1,532,984	1.31
Vested	(1,526,109)	1.29
Non vested at September 30, 2019	6,875	$ 6.24
Total unrecognized expense remaining	$ 39,138	
Weighted-average years expected to be recognized over	0.5	

During the year ended September 30, 2019, Private NeuBase sold restricted stock to consultants for services to be provided to Private NeuBase and entered into related restricted stock agreements. The gross proceeds from the sale of the restricted stock was $1,474. The restricted stock was scheduled to vest over a period of 3 years, subject to accelerated vesting upon certain performance targets. Upon closing of the Ohr Acquisition, Private NeuBase accelerated the vesting of the restricted stock issued to the consultants.

The Company recorded stock-based compensation expense in the following expense categories of its consolidated statements of operations for the year ended September 30, 2019 and for the period from August 28, 2018 (inception) to September 30, 2018:

	For the Year Ended September 30, 2019	For the Period From August 28, 2018 (Inception) to September 30, 2018
General and administrative expenses	$ 6,543,575	$ -
Research and development expenses	3,241,508	-
	$ 9,785,083	$ -

9. Income Taxes

The Company has accumulated net losses since inception and has not recorded an income tax provision or benefit for the United States (U.S.) federal and state income taxes during the year ended September 30, 2019 and for the period from August 28, 2018 (inception) to September 30, 2018.

A reconciliation of income taxes at the statutory federal income tax rate to net income taxes included in the consolidated statements of operations is as follows:

	For the Year Ended September 30, 2019	For the Period From August 28, 2018 (Inception) to September 30, 2018
U.S. federal income tax expense at the statutory rate	(21.0)%	(21.0)%
State income taxes, net of federal taxes	(7.9)	(7.9)
Stock-based compensation	0.4	-
Ohr acquisition	12.8	-
Change in valuation allowance	15.0	28.4
Other permanent items	0.7	0.5
Income tax provision (benefit)	0%	0%

The components of our deferred tax assets and liabilities are:

	September 30,	
	2019	2018
Deferred tax assets		
Net operating loss carryforwards	$ 1,840,194	$ 11,907
Stock-based compensation	2,161,121	-
Amortization	286,526	-
Total deferred tax assets	4,287,841	11,907
Deferred tax liabilities		
Depreciation	(19,310)	-
Prepaid expenses	(205,116)	-
Total deferred tax liabilities	(224,426)	-
Valuation allowance	(4,063,415)	(11,907)
Net deferred tax assets, net of allowances	$ -	$ -

As of each reporting date, the Company considers existing evidence, both positive and negative, that could impact its view with regard to future realization of deferred tax assets. The Company believes that it is more likely than not that the benefit for deferred tax assets will not be realized. In recognition of this uncertainty, a full valuation allowance was applied to the deferred tax assets. The Company did not record a tax provision for the year ended September 30, 2019 and for the period August 28, 2018 (inception) through September 30, 2018, due to the Company's estimate that the effective tax rate for each year is 0%.

Future realization depends on the Company's future earnings, if any, the timing and amount of which are uncertain as of September 30, 2019. In the future, should management conclude that it is more likely than not that the deferred tax assets are partially or fully realizable, the valuation allowance would be reduced to the extent of such expected realization and the amount would be recognized as a deferred income tax benefit in the Company's consolidated statements of operations.

As of September 30, 2019, the Company had available total net operating loss carryforwards of approximately $6.4 million. Federal net operating losses of approximately $6.3 million carryforward indefinitely. State operating loss carryforwards of approximately $6.4 million, begin to expire in 2039.

Pursuant to Section 382 of the Internal Revenue Code of 1986, as amended, the Company's federal and state net operating loss carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has not completed a Section 382 analysis regarding the limitation of net operating loss carryforwards. There is a risk that changes in ownership have occurred since Company's formation. If a change in ownership were to have occurred, the NOL carryforwards could be limited or restricted. If limited, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance. Due to the existence of the valuation allowance, limitations created by future ownership changes, if any, related to the Company's operations will not impact the Company's effective tax rate.

There are open statutes of limitations for taxing authorities in federal and state jurisdictions to audit our tax returns from inception of the Company. There have been no material income tax related interest or penalties assessed or recorded.

No liability related to uncertain tax positions is reported in the Company's consolidated financial statements.

10. Equipment

The Company's equipment consisted of the following:

	September 30,		Estimated Useful Life (in years)
	2019	2018	
Laboratory equipment	$ 452,817	$ -	5
Office equipment	2,383	-	3
	455,200	-	
Accumulated depreciation	(24,205)	-	
	$ 430,995	$ -	

Depreciation expense for the years ended September 30, 2019 was approximately $24,000. Depreciation expense for the period August 28, 2018 (inception) through September 30, 2018 was $0.

11. Intangible Assets

The Company's intangible assets consisted of the following:

	September 30,		Estimated useful life (in months)
	2019	2018	
Clinical trial data	$ 250,000	$ -	6
Accumulated amortization	(104,167)	-	
Intangible assets, net	$ 145,833	$ -	

Amortization expense for the years ended September 30, 2019 was approximately $104,000. Amortization expense for the period August 28, 2018 (inception) through September 30, 2018 was $0.

12. Joint Venture

On February 26, 2014, Ohr entered into a Joint Venture Agreement and related agreements with Cold Spring Harbor Laboratory ("CSHL") pursuant to which a joint venture, DepYmed Inc. ("DepYmed"), was formed to further preclinical and clinical development of the Company's intellectual property for rare diseases and oncology. DepYmed licenses research from CSHL and intellectual property from the Company.

Following the Ohr Acquisition, the Company owns common and preferred shares of DepYmed, which in aggregate represents approximately 16.75% ownership of DepYmed. In addition, as of September 30, 2019, the Company held two of the six seats on DepYmed's board of directors. The Company accounts for its investment in DepYmed using the equity method of accounting and records its proportionate share of DepYmed's net income and losses in the accompanying consolidated statements of operations. In connection with Ohr Acquisition as described in Note 3, the Company determined the fair value of this investment to be $586,418. As of September 30, 2019 the carrying amount of the Company's investment in DepYmed was $586,418. The Company will record its proportionate share of equity in earnings (losses) of DepYmed in the quarter following DepYmed's reported results.

13. Accrued Expenses

The Company's accrued expenses consisted of the following:

	September 30,	
	2019	2018
Accrued compensation and benefits	$ 34,625	$ -
Accrued interest	10,830	740
Accrued professional fees	156,919	19,074
Accrued research and development	88,553	-
Other accrued expenses	114,672	-
	$ 405,599	$ 19,814

14. Related Party Transactions

During the year ended September 30, 2019, the Company utilized the services of LifeX Labs LLC ("LifeX"). These services included accounting consultation and office space rental. Dietrich Stephan, Private NeuBase CEO, was the CEO and a director of LifeX until December 28, 2018, when he resigned all positions within LifeX. On January 8, 2019, LifeX terminated the agreement with the Company, and accordingly, the Company has no remaining obligations under the agreement. During the year ended September 30, 2019 and the period from August 28, 2018 (inception) to September 30, 2018, the Company paid $10,628 and $1,575, respectively, to LifeX.

15. Commitments and Contingencies

Leases

The Company leases its office and operating space under operating leases expiring at various dates through July 2020. Rent expense under the leases totaled approximately $43,000 and $0 for the year ended September 30, 2019 and for the period from August 28, 2018 (inception) through September 30, 2018, respectively.

The Company recognizes rent expense on a straight-line basis over the lease period and has accrued for rent expense incurred but not yet paid. Future minimum rental payments under operating leases with noncancelable terms as of September 30, 2019 due during the year ended 2020 are approximately $55,000.

Employee Benefit Plans

The Company has a defined contribution savings and investment plan (the "Plan") as allowed under Sections 401(k) and 401(a) of the Internal Revenue Code. The Plan provides employees with tax deferred salary deductions and alternative investment options. Employees are eligible to participate upon employment and may apply for and secure loans from their account in the Plan. The Company did not contribute to the Plan during the year ended September 30, 2019 and for the period from August 28, 2018 (inception) through September 30, 2018.

Litigation

The Company has become involved in certain legal proceedings and claims which arise in the normal course of business. If an unfavorable ruling were to occur, there exists the possibility of a material adverse impact on the Company's results of operations, prospects, cash flows, financial position and brand.

On February 14, 2018, plaintiff, Jeevesh Khanna, commenced an action in the Southern District of New York, against Ohr and several current and former officers and directors of Ohr, alleging that they violated federal securities laws between June 24, 2014 and January 4, 2018. On August 7, 2018, the lead plaintiffs, now George Lehman and Insured Benefit Plans, Inc. filed an amended complaint, stating the class period to be April 8, 2014 through January 4, 2018. The plaintiffs did not quantify any alleged damages in their complaint but, in addition to attorneys' fees and costs, they seek to maintain the action as a class action and to recover damages on behalf of themselves and other persons who purchased or otherwise acquired Ohr common stock during the putative class period and purportedly suffered financial harm as a result. The Company and the individuals dispute these claims and intend to defend the matter vigorously. On September 17, 2018, Ohr filed a motion to dismiss the complaint. On September 20, 2019, the Court entered an order granting the defendants' motion to dismiss. On October 23, 2019, the plaintiffs filed a notice of appeal of that order dismissing the action and other related orders by the Court. Briefing on the appeal is currently scheduled for the first half of 2020. This litigation could result in substantial costs and a diversion of management's resources and attention, which could harm the Company's business and the value of its common stock.

On May 3, 2018, plaintiff Adele J. Barke, derivatively on behalf of Ohr, commenced an action against certain former directors of Ohr, including Michael Ferguson, Orin Hirschman, Thomas M. Riedhammer, June Almenoff and Jason S. Slakter in the Supreme Court, State of New York, alleging that the action was brought in the right and for the benefit of Ohr seeking to remedy their "breach of fiduciary duties, corporate waste and unjust enrichment that occurred between June 24, 2014 and the present." It does not quantify any alleged damages. The Company and the individuals dispute these claims and intend to defend the matter vigorously. Such litigation has been stayed pursuant to a stipulation by the parties, which has been so ordered by the court, pending a decision in the Southern District case on the motion to dismiss, but that status could change. This litigation could result in substantial costs and a diversion of management's resources and attention, which could harm the Company's business and the value of its common stock.

On March 20, 2019, a putative class action lawsuit was filed in the United States District Court for District of Delaware naming as defendants Ohr and its board of directors, Private NeuBase, and Merger Sub, captioned *Wheby v. Ohr Pharmaceutical, Inc., et al*, Case No. 1:19-cv-00541-UNA (the "Wheby Action"). The plaintiffs in the Wheby Action allege that the preliminary joint proxy/prospectus statement filed by Ohr with the Securities and Exchange Commission ("SEC") on March 8, 2019 contained false and misleading statements and omitted material information in violation of Section 14(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and SEC Rule 14a-9 promulgated thereunder, and further that the individual defendants are liable for those alleged misstatements and omissions under Section 20(a) of the Exchange Act. The complaint in the Wheby Action has not been served on, nor was service waived by, any of the named defendants in that action. The action seeks, among other things, to rescind the Ohr Acquisition or an award of damages, and an award of attorneys' and experts' fees and expenses. The defendants dispute the claims raised in the Wheby Action. Management believes that the likelihood of an adverse decision from the sole remaining action is unlikely; however, the litigation could result in substantial costs and a diversion of management's resources and attention, which could harm the Company's business and the value of the Company's common stock.

16. Revisions of Financial Statements (unaudited)

In connection with the preparation of our financial statements, our management and the audit committee of our board of directors determined that our accounting treatment and valuations pertaining to the PATrOL™ technology license, as described in Note 4, should be modified. This change in accounting treatment resulted in an increase in total operating expenses of approximately $0.9 million on our Consolidated Statements of Operations and a decrease in intangible assets of approximately $1.5 million on our Consolidated Balance Sheet. In connection with the valuation adjustments to the PATrOL™ technology license, we also determined that valuations pertaining to certain share-based awards should also be adjusted. This change in valuation to share-based awards resulted in a decrease in total operating expenses of approximately $0.3 million on our Consolidated Statements of Operations.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act, is recorded, communicated to our management to allow timely decisions regarding required disclosure, summarized and reported within the time periods specified in the SEC's rules and forms.

Under the supervision and with the participation of our management, including our CEO and Chief Financial Officer ("CFO") who serve as the principal executive officer and the principal financial officer, respectively, we conducted an evaluation of the effectiveness of our disclosure controls and procedures, as such term is defined under Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of September 30, 2019. Based on this evaluation, our CEO and CFO concluded that our disclosure controls and procedures were not effective as of September 30, 2019 due to a material weakness in our internal control over financial reporting due to a lack of expertise in complex accounting transactions. As of the date of this Annual Report on Form 10-K, our CEO and CFO believe that this material weakness has been remedied, as we have hired a financial accounting consultant to provide accounting advisory services.

Management's Report on Internal Control Over Financial Reporting

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). Our internal control over financial reporting is a process designed by, under the supervision and, with the participation of our CEO and CFO who serve as our principal executive officer and principal financial officer, respectively, overseen by our board of directors and implemented by our management and other personnel, to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes policies and procedures that:

(1) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
(2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
(3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, our internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Management performed an assessment of the effectiveness of our internal control over financial reporting as of September 30, 2019 using criteria established in the *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on this assessment, management determined that, as of September 30, 2019, our internal control over financial reporting was not effective due to a material weakness. Because we are a non-accelerated filer and smaller reporting company, CohnReznick LLP, an independent registered public accounting firm, is not required to attest to or issue a report on the effectiveness of our internal control over financial reporting.

In connection with the preparation of our financial statements, our management and the audit committee of our board of directors determined that our accounting treatment and valuations pertaining to the PATrOL™ technology license should be modified. This change in accounting treatment resulted in an increase in total operating expenses of approximately $0.9 million on our Consolidated Statements of Operations and a decrease in intangible assets of approximately $1.5 million on our Consolidated Balance Sheet. In connection with the valuation adjustments to the PATrOL™ technology license, we also determined that valuations pertaining to certain share-based awards should also be adjusted. This change in valuation to share-based awards resulted in a decrease in total operating expenses of approximately $0.3 million on our Consolidated Statements of Operations. In connection with such revisions, our management identified a material weakness in our internal control over financial reporting due to a lack of expertise in complex accounting transactions, which were not operating effectively to provide reasonable assurance that complex transaction were accounted for correctly.

During 2019, we undertook remediation measures by hiring a financial accounting consultant to provide accounting advisory services on complex transactions and accounting matters.

Accordingly, our CEO and CFO concluded that, at September 30, 2019, our internal control over financial reporting was not effective. Notwithstanding the material weaknesses in our internal control over financial reporting, based on the additional analyses and procedures performed, we believe the consolidated financial statements included in our Annual Report on Form 10-K are fairly presented in all material respects, in conformity with accounting principles generally accepted in the United States of America.

Inherent Limitations on Effectiveness of Controls

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure system are met. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

As noted above, to remediate a material weakness in in our internal control over financial reporting due to a lack of expertise in complex accounting transactions, we hired a financial accounting consultant to provide accounting advisory services on complex transactions and accounting matters. There were no other changes in our internal control over financial reporting during the fiscal year ended September 30, 2019, that have materially affected, or are 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

Name	Age[1]	Position
Non-Employees Directors		
Dov A. Goldstein, M.D. [2] [4]	52	Director
Diego Miralles, M.D. [3] [4]	57	Director
Franklyn G. Prendergast, M.D., Ph.D. [2] [4]	74	Director
Eric I. Richman [2] [3]	58	Director
Executive Officers		
Dietrich Stephan, Ph.D.	50	President, Chief Executive Officer and Director
Sam Backenroth	35	Chief Financial Officer, Treasurer and Secretary

(1) Ages as of September 30, 2019.

(2) Member of the Audit Committee.

(3) Member of the Corporate Governance/Nominating Committee.

(4) Member of the Compensation Committee.

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

Board of Directors

Dietrich Stephan, Ph.D., 50, has been our President, Chief Executive Officer and a member of our board of directors since July 2019. Dr. Stephan was also the founder and Chief Executive Officer of Legacy NeuBase. Before founding NeuBase, Dr. Stephan was founder and Chief Executive Officer of LifeX Holdings, a healthcare startup incubator, and a tenured full professor of Human Genetics at the University of Pittsburgh. He served as Chair of the Department of Human Genetics at the University of Pittsburgh from 2013 to 2018, and earlier, as the founding Director of the Neurogenomics Division at the Translational Genomics Research Institute (TGen) and Deputy Director of Discovery Research at TGen. Dr. Stephan is Chairman of Peptilogics, a privately held peptide therapeutics company; a director of Sharp Edge Labs, a privately held small-molecule genetic disease therapeutics company; a director of FarmaceuticalRx, a privately held pharmaceutical company developing cannabinoid-based therapies; a director of Epistemix, a population-based disease modeling company; and partner in Cyto Ventures, an early stage investment fund. In the last five years, Dr. Stephan has held director roles at Pendulum Therapeutics (formerly Whole Biome), a privately held company developing microbiome therapies; CereDx, a privately held home-base stroke detection diagnostics company; Elastogenesis, a privately held pharmaceutical company developing therapies for dermal extracellular matrix regeneration; Western Oncolytics, a privately held pharmaceutical company developing oncolytic viruses; iGenomX, a privately held company developing genome sequencing reagents; Ariel Precision Medicine, a privately held diagnostics company focused on pancreatic disease; and ParaBase, a privately held company focused on developing neonatal genetic diagnostic tests.

Dr. Stephan received his B.S. in Biology from Carnegie Mellon University and his Ph.D. in Human Genetics from the University of Pittsburgh. He also completed a fellowship at the National Human Genome Research Institute. We believe that Dr. Stephan's role as CEO of our Company, experience as the founder of Legacy NeuBase and in the biopharmaceutical industry qualify him to serve as a member of our board of directors.

Dov A. Goldstein, M.D., 52, has served as a member of our board of directors since July 2019. Dr. Goldstein is currently a private investor. Dr. Goldstein previously was the Chief Financial Officer at Schrödinger, LLC from the fourth quarter of 2017 to the second quarter of 2018. Dr. Goldstein served as a Managing Partner at Aisling Capital, a private investment firm, from 2014 to October 2017, Partner from 2008 to 2014 and a principal at Aisling Capital from 2006 to 2008. Dr. Goldstein served as the Chief Financial Officer of Loxo Oncology, Inc. between July 2014 and January 2015, and was its acting Chief Financial Officer from January 2015 to May 2015. From 2000 to 2005, Dr. Goldstein served as Chief Financial Officer of Vicuron Pharmaceuticals, Inc., which was acquired by Pfizer, Inc. in September 2005. Prior to joining Vicuron, Dr. Goldstein was Director of Venture Analysis at HealthCare Ventures. Dr. Goldstein also completed an internship in the Department of Medicine at Columbia-Presbyterian Hospital. Dr. Goldstein serves as a director at ADMA Biologics, Inc. (Nasdaq: ADMA). He also previously served as a director of Loxo Oncology, Inc. (Nasdaq: LOXO), Esperion Therapeutics, Inc. (Nasdaq: ESPR), and Cempra, Inc. (which was acquired by Melinta Therapeutics, Inc.). Dr. Goldstein received a B.S. from Stanford University, an M.B.A. from Columbia Business School and an M.D. from Yale School of Medicine.

We believe that Dr. Goldstein's medical training and his experience in the biopharmaceutical industry as a venture capital investor, as an executive of Vicuron and a member of the boards of directors of other biopharmaceutical companies, as well as his experience in financial matters and his service on compensation committees, qualify him to serve as a member of our board of directors.

Diego Miralles, M.D., 57, has served as a member of our board of directors since July 2019. Dr. Miralles is currently the Chief Executive Officer of Vividion Therapeutics, Inc., a biotechnology company with a platform to discover and develop small molecule therapeutics, and has served in that role since August 2017. Prior to briefly serving as President of Adaptive Therapeutics, Inc. during 2016 and 2017, Dr. Miralles had an extensive career at Johnson & Johnson, culminating in his position as the Global Head of Innovation, and was involved in the development and approval of PREZISTA® and INTELENCE®. He was the head of the Janssen Research and Early Development unit in La Jolla, CA. While at Johnson & Johnson, he founded and launched the JLABS incubator in 2012 for start-up life science entrepreneurs, and was instrumental in developing and launching Johnson & Johnson's Innovation center model in 2013. He was a member of the management committee at Janssen, one of the largest pharmaceutical companies in the world. He was also a member of the management board of Tibotec BVBA, a leading virology company and a Johnson & Johnson company. Prior to Johnson & Johnson, Dr. Miralles held R&D positions at Trimeris, Inc. and Triangle Pharmaceuticals, Inc., and he was an Assistant Professor at Duke University Medical Center, where he was a bench scientist and an Infectious Disease physician, with a focus on HIV. Dr. Miralles is currently an Adjunct Professor in the Department of Pharmacology at the University of California San Diego. He received his M.D. degree from the Universidad de Buenos Aires, Argentina, completed his internal medicine residency at the Mayo Clinic and was a fellow in Infectious Diseases at Cornell University-New York Hospital.

We believe that Dr. Miralles's extensive experience in the biotechnology industry, and in particular his current service as a chief executive officer and his prior service in executive management roles at Johnson & Johnson, provide him with the qualifications and skills to serve as a member of our board of directors.

Franklyn G. Prendergast, M.D., Ph.D., 74, has served as a member of our board of directors since July 2019. Dr. Prendergast retired from the Mayo Clinic in 2014 and is currently the Emeritus Edmond and Marion Guggenheim Professor of Biochemistry and Molecular Biology and Emeritus Professor of Molecular Pharmacology and Experimental Therapeutics at Mayo Medical School. At the Mayo Clinic, he served in several capacities, most significantly, as the Director for Research 1989 – 1992, inclusive, Member of the Mayo Clinic Board of Governors and Executive Committee 1991 – 2007, and Member of the Mayo Clinic Board of Trustees from 1991-2009, inclusive. From 1994 to 2006, he served as a director of Mayo Clinic Cancer Center. He also previously held several other teaching positions at the Mayo Medical School from 1975 through 2014. Dr. Prendergast has served for the National Institute of Health on numerous study section review groups; as a charter member of the Board of Advisors for the Division of Research Grants, now the Center for Scientific Review; the National Advisory General Medical Sciences Council; and the Board of Scientific Advisors of the National Cancer Institute. He held a Presidential Commission for service on the National Cancer Advisory Board. Dr. Prendergast also has served in numerous other advisory roles for the National Institute of Health and the National Research Council of the National Academy of Sciences. He is a member of the board of directors of Cancer Genetics, Inc. (Nasdaq: CGIX) and a member of the board's audit, compensation and nominating committees. He is also a member of the board of directors of Medibio Limited (ASX:MEB) (OTCQB:MDBIF) and the Infectious Disease Research Institute (IDRI), and he previously served on the board of directors of Eli Lilly & Co. from 1995 to 2017 and was a member of the board's science and technology committee and public policy and compliance committee. Dr. Prendergast obtained his medical degree with honors from the University of West Indies and attended Oxford University as a Rhodes Scholar, earning an M.A. degree in physiology. He obtained his Ph.D. in Biochemistry at the University of Minnesota.

We believe that Dr. Prendergast's extensive experience and expertise as a medical clinician, researcher and academician, particularly in the areas of oncology and personalized medicine, developed through his roles with Mayo Clinic, including serving as director of the Mayo Clinic Cancer Center and the Mayo Clinic Center for Individualized Medicine, qualify him to serve as a member on our board of directors.

Eric I. Richman, 58, has served as a member of our board of directors since July 2019. Mr. Richman was previously a Venture Partner at Brace Pharma Capital, a life science venture capital firm, from January 2016 to September 2018 and is involved with several private and public biotechnology companies. He also served as Chief Executive Officer of Tyrogenex Inc., a biopharmaceutical company, from 2016 to 2018. Mr. Richman served as the President and Chief Executive Officer of PharmAthene, Inc. ("PharmAthene"), subsequently acquired by Altimmune, Inc., between October 2010 and March 2015. He also served on PharmAthene's board of directors, when the company was listed on the NYSE, from 2010 to 2017. Prior to joining PharmAthene, Mr. Richman held various commercial and strategic positions of increasing responsibility over a 12-year period at MedImmune, Inc. from its inception and was Director, International Commercialization at that company. Mr. Richman served as a director of Lev Pharmaceuticals, Inc. (acquired by Viropharma) and as Chairman of its Commercialization Committee and served as a director of American Bank Incorporated (acquired by Congressional Bancshares). Mr. Richman currently serves as a director of Adma Biologics, Inc. (Nasdaq: ADMA) (as well as a member of such board's audit, compensation and governance and nominating committees), Zyversa Pharmaceuticals, Inc., NovelStem International Corp. (OTCMKTS: NSTM), co-founder and director of InFuse Holdings and LabConnect, Inc. where he serves as the Chairman of the Board. Mr. Richman received a B.S. in Biomedical Science from the Sophie Davis School of Biomedical Education (CUNY Medical School) and a M.B.A. from the American Graduate School of International Management.

We believe that Mr. Richman's experience in the biotechnology industry, including his successful efforts in gaining FDA drug approvals, as well as his experience as an executive officer of PharmAthene and his service on numerous public and private company boards of directors and on the committees of such boards, provide him with the qualifications and skills to serve as a member of our board of directors.

Executive Officers

Dietrich Stephan, Ph.D. For a brief biography of Dr. Stephan, please see "DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE – Board of Directors" above.

Sam Backenroth, age 35, has served as our Chief Financial Officer since July 2019. Mr. Backenroth previously served as Chief Financial Officer and Vice President of Business Development of Ohr from April 2010 to July 2019, has been a Director of DepYmed, since 2014, and a founder of Orphion Therapeutics, since 2018. Mr. Backenroth has previously worked as an investment banker with The Benchmark Company LLC, an investment banking firm specializing in micro-cap biotech transactions. While at Benchmark, he helped fund numerous small biotech companies raise growth equity capital through a variety of structures. Mr. Backenroth also acted as an advisor to public and private biotech companies in assisting with business development activities, joint ventures, licensing, strategic partnerships, and mergers & acquisitions. He graduated with honors from Touro College with a Bachelors degree in finance.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act requires our executive officers, directors and persons who beneficially own greater than 10% of a registered class of its equity securities to file certain reports with the SEC with respect to ownership and changes in ownership of the our common stock and our other equity securities.

To our knowledge, based solely on our review of the copies of such reports filed with the SEC, our officers, directors and greater than 10% stockholders timely complied with these Section 16(a) filing requirements during the fiscal year ended September 30, 2019.

Code of Ethics

We have adopted a Code of Conduct and Ethics, as amended, that applies to our Chief Executive Officer and to all of our other officers, directors and employees. The Code of Conduct and Ethics is available in the Governance section of the Investors page on our website at www.neubasetherapeutics.com. We will disclose future amendments to, or waivers from, certain provisions of our Code of Conduct and Ethics, if any, on the above website within four business days following the date of such amendment or waiver.

Audit Committee

We have a separately-designated standing audit committee established in accordance with Section 3(a)(58)(A) of the Exchange Act. Our audit committee currently consists of Dr. Dov A. Goldstein (Chair), Dr. Franklyn G. Prendergast, and Eric I. Richman. All are non-employee directors and are considered independent under the applicable independence standard promulgated by The Nasdaq Stock Market LLC ("Nasdaq") and the SEC. Our board of directors has currently designated each of Dr. Goldstein and Mr. Richman as an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K. We believe that the audit committee members are capable of analyzing and evaluating our financial statements and understanding internal control over financial reporting.

Compensation Committee

Our Compensation Committee is currently comprised of Dr. Franklyn G. Prendergast (Chair), Dr. Dov A. Goldstein, Dr. Diego Miralles, each of whom is an independent director for purposes of the Nasdaq listing standards. The Compensation Committee reviews and recommends executive compensation, including changes therein, and administers our equity compensation plans.

Compensation Committee Membership, Interlocks and Insider Participation

Each member of the Compensation Committee is a "non-employee" director within the meaning of Rule 16b-3 of the rules promulgated under the Exchange Act. None of Drs. Prendergast, Goldstein, or Miralles is an officer or employee of ours, was formerly an officer of ours or had any relationship requiring disclosure by us under Item 404 of Regulation S-K. No interlocking relationship as described in Item 407(e)(4) of Regulation S-K exists between any of our executive officers or Compensation Committee members, on the one hand, and the executive officers or compensation committee members of any other entity, on the other hand, nor has any such interlocking relationship existed in the past.

Corporate Governance/Nominating Committee

Our Corporate Governance/Nominating Committee currently consists of Dr. Diego Miralles (Chair) and Eric I. Richman. Both are non-employee directors and are considered independent under the applicable independence standard promulgated by Nasdaq and the SEC.

Material Changes to Procedures By Which Security Holders May Recommend Nominees to the Board of Directors

On September 19, 2019, our board of directors adopted the Amended and Restated Bylaws of the Company, effective as of such date (the "Restated Bylaws"). The Restated Bylaws primarily updated our prior bylaws (the "Prior Bylaws") to include and update provisions commonly found in the bylaws of public Delaware corporations similar to us.

Article III, Sections 5 and Section 6 of the Restated Bylaws (the "Advance Notice Provisions") amend the Prior Bylaws to describe the manner and timeframes in which our stockholders may properly bring business before, or nominate any person for election to our board of directors at an annual or special meeting of stockholders. The Advance Notice Provisions set forth the various eligibility requirements that must be met by (a) any stockholder who wishes to bring such business before an annual or special meeting of stockholders and (b) any nominee for election to our board of directors. The Advance Notice Provisions also describe the substantive and procedural requirements that a stockholder must comply with in order to properly bring business, including the nomination of any person for election to our board of directors, before an annual or special meeting.

Among other requirements, the Advance Notice Provisions provide that: (i) a stockholder must provide to the secretary of the Company timely notice of any business, including director nominations, proposed to be brought before the annual or special meeting, which notice must conform to the substantive requirements set forth in the Restated Bylaws; (ii) a stockholder must deliver certain information regarding the person making the proposal, and in the case of any nominee for election to our board of directors, information regarding such nominee, in each case as set forth in the Restated Bylaws, and update and supplement such information as required; and (iii) any nominee for election to our board of directors must provide both a written questionnaire regarding such nominee's background and qualifications, and a written representation and agreement regarding voting commitments, indemnification or similar arrangements and compliance with our policies applicable to members of our board of directors.

The Prior Bylaws contained advance notice provisions and procedures for our stockholders to bring business before, or nominate persons for election to our board of directors at, annual or special meetings of stockholders; however, they did not, among other things: (A) require certain information or disclosures with respect to the proposing or nominating stockholder(s), stockholder nominees and stockholder proposals; or (B) require updating of information or disclosures contained within the notice.

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth the compensation paid by us during the years ended September 30, 2019 and 2018 to (1) our principal executive officer during fiscal year 2019 and (2) our only other executive officer who was serving as an executive officer as of September 30, 2019 (collectively our "Named Executive Officers"):

Name and Position	Year	Salary	Bonus (1)	Stock Awards (2)	Option Awards (3)	Non-Equity Incentive Plan Compensation	All Other Compensation (4)	Total
Dietrich Stephan, Ph.D., Chief Executive Officer	2019	$ 135,577	$ 175,000	$ —	$ 3,347,500	$ —	$ 19,199	$ 3,677,276
	2018	$ —(5)	$ —	$ 25	$ —	$ —	$ —	$ 25
Sam Backenroth, Chief Financial Officer	2019	$ 223,539	$ 95,000	$ —	$ 2,937,107	$ —	$ 18,618	$ 3,274,264
	2018	$ 200,000	$ —	$ —	$ 152,007	$ —	$ 18,146	$ 370,153
Jason S. Slakter, M.D., Former Chief Executive Officer (6)	2019	$ 161,539	$ —	$ —	$ —	$ 75,000(8)	$ 163	$ 236,702
	2018	$ 220,000(7)	$ —	$ —	$ 169,379	$ —	$ 195	$ 389,574

(1) No bonuses were awarded for service in fiscal 2018. In the fiscal year ended September 30, 2019, Dr. Stephan received a $175,000 bonus upon the completion of the Merger, and Mr. Backenroth received a $95,000 signing bonus following the Merger pursuant his employment offer letter, dated May 22, 2019.

(2) The amounts in this column reflect the grant date fair value of restricted stock granted during the fiscal year 2018. The grant date fair value was computed by multiplying the number of shares of restricted stock by the purchase price of each share of restricted stock in accordance with FASB ASC Topic 718.

(3) The amounts in this column reflect the aggregate grant date fair value of equity awards granted during the applicable fiscal year, calculated in accordance with FASB ASC Topic 718 and using a Black-Scholes valuation model. Assumptions used in the calculation of these amounts are included in Note 8 of the audited financial statements.

(4) Consists of other compensation amounts for each named executive officer listed in the table entitled "All Other Compensation" below, including our contributions to such officers' 401(k), group term life insurance policy premiums, health benefits and paid time off buy back.

(5) No salaries were paid for Dr. Stephan's service in the fiscal year 2018.

(6) Dr. Slakter's resigned from Ohr on July 12, 2019 in connection with the Merger.

(7) Includes payments for service on the Ohr board of directors.

(8) Includes severance of $75,000 paid to Dr. Slakter upon his resignation at the closing of the merger.

All Other Compensation

Name	Year	401(k) Company	Group Term	Health Benefits	Paid Time Off Buy Back	Total Other Compensation
Dietrich Stephan, Ph.D.	2019	—	$ 239	18,960	—	$ 19,199
Chief Executive Officer	2018	—	$ —	—	—	$ —
Sam Backenroth	2019	—	$ 195	$ 18,423	—	$ 18,618
Chief Financial Officer	2018	—	$ 195	$ 17,951	—	$ 18,146
Jason S. Slakter, M.D.	2019	—	$ 163	—	—	$ 163
Former Chief Executive Officer	2018	—	$ 195	—	—	$ 195

Narrative Disclosure to Summary Compensation Table

Base Salary

In general, base salaries for our Named Executive Officers are approved by the compensation committee of our board of directors (the "Compensation Committee") and are initially established through arm's length negotiation at the time the executive is hired, taking into account such executive's qualifications, experience, prior salary and market pay levels. Base salaries of our Named Executive Officers are approved and reviewed annually by our Compensation Committee and adjustments to base salaries are based on the scope of an executive's responsibilities, individual contribution, prior experience and sustained performance. Decisions regarding salary increases may take into account an executive officer's current salary, equity ownership, and the amounts paid to an executive officer's peers inside our company by conducting an internal analysis, which compares the pay of an executive officer to other members of the management team. Base salaries are also reviewed in the case of promotions or other significant changes in responsibility. Base salaries are not automatically increased if the Compensation Committee believes that other elements of the Named Executive Officer's compensation are more appropriate in light of our stated objectives. This strategy is consistent with our intent of offering compensation that is both cost-effective, competitive and contingent on the achievement of performance objectives.

With the exception of a raise in Mr. Backenroth's base salary in July 2019 made in connection with his employment offer letter, dated May 22, 2019, our Named Executive Officers did not receive base salary increases in 2019 or 2018.

Equity Compensation

The Compensation Committee considers equity incentives to be important in aligning the interests of our executive officers with those of our stockholders. As part of our pay-for-performance philosophy, our compensation program tends to emphasize the long-term equity award component of total compensation packages paid to our executive officers.

Because vesting is based on continued employment, our equity-based incentives also encourage the retention of our Named Executive Officers through the vesting period of the awards. In determining the size of the long-term equity incentives to be awarded to our Named Executive Officers, we take into account a number of internal factors, such as the relative job scope, the value of existing long-term incentive awards, individual performance history, prior contributions to us and the size of prior grants. Based upon these factors, the Compensation Committee determines the size of the long-term equity incentives at levels it considers appropriate to create a meaningful opportunity for reward predicated on the creation of long-term stockholder value.

To reward and retain our Named Executive Officers in a manner that best aligns employees' interests with stockholders' interests, we use stock options and restricted stock unit awards as the primary incentive vehicles for long-term compensation. We believe that stock options and restricted stock unit awards are effective tools for meeting our compensation goal of increasing long-term stockholder value by tying the value of the stock to our future performance. Because employees are able to profit from stock options only if our stock price increases relative to the stock option's exercise price, we believe stock options provide meaningful incentives to employees to achieve increases in the value of our stock over time.

We use stock options, and may also use and restricted stock unit awards, to compensate our Named Executive Officers both in the form of initial grants in connection with the commencement of employment and annual refresher grants. While we intend that the majority of equity awards to our employees be made pursuant to initial grants or our annual grant program, the Compensation Committee retains discretion to grant equity awards to employees at other times, including in connection with the promotion of an employee, to reward an employee, for retention purposes or for other circumstances recommended by management or the Compensation Committee.

The exercise price of each stock option grant is the fair market value of our common stock on the grant date. Time-based stock option awards granted to Dr. Stephan provided for vesting over a four-year period in equal monthly installments over 48 months. Dr. Stephan's time-based stock option awards vested immediately and became exercisable upon the consummation of the Merger. Time-based stock option awards to Mr. Backenroth provided for vesting over a four-year period as follows: 25% of the shares underlying the option vest on the first anniversary of the date of the vesting commencement date and the remainder of the shares underlying the option vest in equal monthly installments over the remaining 36 months thereafter. Time-based stock option awards granted to Dr. Slakter vest over a three-year period, with one-third of the shares underlying the option vesting on each anniversary of the vesting commencement date. Dr. Slakter's options fully vested at the closing of the Merger upon the termination of Dr. Slakter's service with us. From time to time, our Compensation Committee may, however, determine that a different vesting schedule is appropriate. We do not have any stock ownership requirements for our Named Executive Officers.

Outstanding Equity Awards as of September 30, 2019

The following table shows information regarding our outstanding equity awards as of September 30, 2019 for the Named Executive Officers:

	Option Awards					Stock Awards			
Name	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Non-Exercisable (#)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($)
Dietrich Stephan, Ph.D.	3,311,930	—	—	$ 0.001	12/31/2028(1)	—	—	—	$ —
Sam Backenroth	—	772,923(2)	—	$ 5.39	7/12/2029(1)	—	—	—	—
	17,500(3)	—	—	$ 13.40	10/15/2022(4)	—	—	—	—
Jason S. Slakter, M.D.	19,500(3)	—	—	$ 13.40	10/15/2022(4)	—	—	—	—

(1) The options have a term of 10 years from the date of issuance.

(2) The stock option vests over four years from the date of grant of July 12, 2019, with 25% of the shares subject to the options vesting on the first anniversary of the date of grant and the remainder vesting in 36 monthly tranches thereafter.

(3) The option vested over a three-year period, with one-third of the shares underlying the option vesting on each of October 16, 2017, October 16, 2018 and October 16, 2019; provided that the last one-third vested in full in connection with the closing of the Merger.

(4) The options have a term of five years from the date of issuance.

Stock Vested Table

The table below provides information on the vesting of restricted stock held by Dr. Stephan during the fiscal year ended September 30, 2019. None of our other Named Executive Officers vested any stock during the fiscal year ended September 30, 2019.

	Stock Awards[1]	
Name and Principal Position	**Number of Shares Acquired on Vesting (#)**	**Value Realized on Vesting ($)**
Dietrich A. Stephan Chief Executive Officer	2,547,639	$ 25

(1) The restricted stock awards were granted to Dr. Stephan under the Restricted Stock Purchase Agreement, dated September 6, 2018, by and between NeuBase and Dr. Stephan, and as amended by that certain Amendment to Restricted Stock Purchase Agreement, dated December 22, 2018. The value realized on vesting reflects the grant date fair value of restricted stock granted during the fiscal year ended September 30, 2018. The grant date fair value was computed by multiplying the number of shares of restricted stock by the purchase price of each share of restricted stock in accordance with FASB ASC Topic 718.

Payments Upon Termination or Change In Control

We have entered into employment agreements with each of our Named Executive Officers. These agreements set forth the individual's base salary, annual incentive opportunities, equity compensation and other employee benefits, which are described in this Executive Compensation section. All employment agreements provide for "at-will" employment, meaning that either party can terminate the employment relationship at any time, although our agreements with our Named Executive Officers provide that they would be eligible for severance benefits in certain circumstances following a termination of employment without cause. Our Compensation Committee approved the severance benefits to mitigate certain risks associated with working in a biopharmaceutical company at our current stage of development and to help attract and retain qualified executives.

Dietrich Stephan, Ph.D.

Historically, Legacy NeuBase had one executive officer, Dietrich Stephan, Ph.D., President and Chief Executive Officer. Upon the formation of Legacy NeuBase and until the date that Legacy NeuBase and Dr. Stephan entered into an employment agreement, in recognition of our low levels of operating cash flow and Dr. Stephan's status as a stockholder of Legacy NeuBase, he forewent any cash compensation for his service as an executive officer.

Legacy NeuBase entered into an employment agreement as of December 22, 2018 with Dr. Stephan as its Chief Executive Officer, effective as of August 28, 2018 (the "Stephan Employment Agreement"). Beginning on December 22, 2018, Dr. Stephan's annual base salary was $75,000. If Legacy NeuBase issued and sold shares of its preferred or common stock in one or a series of transactions for aggregate proceeds of at least $4,000,000 (excluding all proceeds realized from the conversion or cancellation of debt in exchange for the issuance of such stock) ("Qualified Financing"), Dr. Stephan's annual base salary would be increased to $450,000, and Legacy NeuBase would pay Dr. Stephan an additional $2,000 per month for his supplemental life and disability insurance policies. Dr. Stephan's annual base salary is subject to increase or decrease by Legacy NeuBase's board of directors or a committee duly appointed by the board.

On or about December 28, 2018, Legacy NeuBase paid Dr. Stephan a bonus of $25,000. Upon the consummation of a Qualified Financing, Dr. Stephan would be eligible for a bonus of $150,000 (the "Bonus"), which may be modified from time to time in the discretion of Legacy NeuBase's board of directors, and would additionally be eligible for an annual bonus of $150,000 ("Annual Bonus") based on the attainment of individual and Legacy NeuBase performance objectives as may be set by Legacy NeuBase's board of directors.

Under the Stephan Employment Agreement, on December 31, 2018, Dr. Stephan was also granted a stock option to purchase 3,250,000 shares of Legacy NeuBase common stock with an exercise price of $0.001 per share. Beginning on August 28, 2018, this stock option began to vest on an equal monthly basis over a 48-month period, subject to Dr. Stephan's continued employment with Legacy NeuBase. Upon completion of the Merger, however, this stock option vested in full, and Dr. Stephan was entitled to exercise his option to purchase 3,311,930 of the combined company's stock at an exercise price adjusted for the exchange ratio pursuant to the Merger Agreement.

Dr. Stephan's employment with Legacy NeuBase was at-will, meaning either Legacy NeuBase or Dr. Stephan could terminate the employment relationship at any time, with or without cause. If Legacy NeuBase terminated Dr. Stephan's employment without "cause" and not on account of his "disability" or Dr. Stephan resigns his employment for "good reason" (as such terms are defined in the Stephan Employment Agreement), then, so long as Dr. Stephan complies with certain obligations, including execution and delivery of a general release within a specified period of time, Legacy NeuBase would pay Dr. Stephan: (1) his base salary as of the termination date for 12 months following the termination date; and (2) subject to the discretion of Legacy NeuBase's board of directors, a pro-rata Bonus or Annual Bonus for the year in which the termination occurs, calculated based on the product of the Dr. Stephan's target Bonus or Annual Bonus times a fraction, the numerator of which is the number of days during the year of termination in which Dr. Stephan was employed and the denominator of which is 365. In addition, 100% of the unvested shares subject to his stock option vest.

Dr. Stephan was also a party to a confidential information, invention assignment and arbitration agreement with Legacy NeuBase, pursuant to which Dr. Stephan has made confidentiality, assignment of intellectual property, nonsolicitation and noncompetition covenants in favor of Legacy NeuBase. Any severance payments that become payable under his employment agreement are conditioned on his compliance with these covenants.

On July 11, 2019, we entered into an Offer of Employment with Dr. Stephan (the "Offer of Employment") that became effective upon the consummation of the Merger on July 12, 2019 and replaced the Stephan Employment Agreement. Pursuant to the Offer of Employment, Dr. Stephan will serve as the Company's President and Chief Executive Officer, his initial annualized salary will be $450,000 and he will be eligible to receive a discretionary annual performance bonus of up to 35% of his base salary. In addition, consistent with the obligations of Legacy NeuBase under the Stephan Employment Agreement, we will pay Dr. Stephan the Bonus pursuant to the completion of the Merger. We paid Dr. Stephan the Bonus on July 19, 2019.

Dr. Stephan's employment with us is at-will, meaning either us or Dr. Stephan could terminate the employment relationship at any time, with or without cause. Pursuant to the Offer of Employment, if Dr. Stephan is terminated by us without cause, we will be obligated to pay to Dr. Stephan (i) severance at a rate equal to 100% of his base salary for a period of 12 months from the date of such termination and (ii) subject to the discretion of our board of directors, a prorated discretionary bonus for the year in which such termination occurs.

In addition, pursuant to the Offer of Employment, Dr. Stephan's confidential information, invention assignment and arbitration agreement with Legacy NeuBase shall continue to apply and was assumed by us.

Jason S. Slakter, M.D.

On August 5, 2015, the Ohr board of directors authorized the restructuring of certain management positions, all of which became effective as of August 7, 2015. Jason S. Slakter, M.D. was appointed Chief Executive Officer of Ohr. During his most recent term as Ohr's chief executive officer, Dr. Slakter was paid an annual base salary of $200,000 and was eligible for equity grants under stockholder approved equity compensation plans.

In connection with the Merger, on January 2, 2019, Ohr entered into a Retention Bonus Agreement with Dr. Jason Slakter, Ohr's former Chief Executive Officer (the "Retention Bonus Agreement"). Under the Retention Bonus Agreement, Dr. Slakter was eligible for a retention bonus payment of $75,000 upon the earliest to occur of the following: (i) the closing of the Merger provided that Dr. Slakter remained in continuous service with us as CEO through and including the closing date of the Merger, or (ii) Dr. Slakter is involuntarily separated from service without Cause (as such term is defined in the Retention Bonus Agreement) by us prior to the closing date of the Merger. In the event Dr. Slakter voluntarily separated from service with us for any reason prior to the closing of the Merger, Dr. Slakter would not receive any retention bonus payment and we would have no further obligation to Dr. Slakter under the Retention Bonus Agreement. The $75,000 bonus was paid to Dr. Slakter in July 2019.

Dr. Slakter resigned from Ohr on July 12, 2019 in connection with the Merger.

Sam Backenroth

On January 6, 2015, Ohr amended its employment agreement with Sam Backenroth, Chief Financial Officer and Vice President, Business Development, to extend the term to February 28, 2016, and to provide for automatic one year extensions thereafter absent notice of termination. The employment agreement provided for an annual base salary of $200,000 for Mr. Backenroth.

Mr. Backenroth was entitled to (1) severance pay and benefits if his employment is terminated, whether at the end of the term of his employment agreement or termination without cause, equal to 50% of his base salary at the time of termination, or (2) alternatively, in the event of a change in control of Ohr, upon (i) his termination without cause, (ii) expiration of the term of his employment agreement, or (iii) as a result of a constructive termination (that is, his resignation because he has reasonably determined in good faith that his titles, authorities, responsibilities, salary, bonus opportunities or benefits have been materially diminished, that a material adverse change in his working conditions has occurred, that his services are no longer required in light of Ohr's business plan, or Ohr has breached his employment agreement) which occurs: (x) concurrently with the change in control, or (y) within 12 months of the change in control, he was entitled to receive (A) severance pay in an amount equal to $400,000, (B) the value of any accrued but unused vacation time, (C) the amount of all accrued but previously unpaid base salary through the date of termination, and (D) all of his then current employment benefits for the longer of twelve (12) months or the full un-expired term of his employment agreement. Mr. Backenroth had the right, for a period of 30 to 90 days following termination of his employment to exercise his Ohr options to the extent such options are otherwise vested and exercisable as of the date of termination. In connection with the Merger, Mr. Backenroth remained our Chief Financial Officer.

On May 22, 2019, Mr. Backenroth entered into a new employment offer letter to serve as our Chief Financial Officer effective upon the consummation of the Merger. Under the terms of the offer letter, which superseded Mr. Backenroth's prior employment agreement with us, Mr. Backenroth will receive a base salary of $320,000 per annum, a signing bonus of $95,000, and a stock option to purchase 772,923 shares of our common stock, allocated from our incentive option pool at an exercise price of $5.39 per share (the "Backenroth Option"), as well as his eligibility to participate in a board-approved benefits and bonus plan. We paid Mr. Backenroth the bonus on July 26, 2019.

Mr. Backenroth's employment with us is at-will, meaning either us or Mr. Backenroth could terminate the employment relationship at any time, with or without cause. If Mr. Backenroth is terminated by us without cause, we will be obligated to pay Mr. Backenroth (1) severance pay at a rate equal to one hundred percent (100%) of his base salary for a period of twelve (12) months from the date of termination, (2) subject to the discretion of our board of directors, a prorated discretionary annual bonus for the year in which the termination occurs. In the event of such termination, 100% of the total number of shares underlying the Backenroth Option shall vest.

Ohr Pharmaceutical, Inc. 2019 Stock Incentive Plan

On March 6, 2019, our board of directors adopted the 2019 Plan to assist us in recruiting and retaining individuals with ability and initiative by enabling them to receive awards and participate in our future success by associating their interests with those of the Company and our stockholders. Our stockholders approved the plan on July 10, 2019. The 2019 Plan is intended to permit the grant of stock options (both incentive stock options ("ISOs") and non-qualified stock options ("NQSOs")), stock appreciation rights ("SARs"), restricted stock ("Restricted Stock Awards"), restricted stock units ("RSUs") and other incentive awards ("Incentive Awards").

The 2019 Plan became effective on the day prior to the closing date of the Merger. No awards may be granted after March 6, 2029, the date which is 10 years after the adoption of the 2019 Plan by our board of directors.

The following is only a summary of the material terms of the 2019 Plan, is not a complete description of all provisions of the 2019 Plan and should be read in conjunction with the 2019 Plan, which is filed as an exhibit to this Annual Report on Form 10-K.

Administration. We bear all expenses of administering the 2019 Plan. The Compensation Committee administers the 2019 Plan. The Compensation Committee has the authority to grant awards to such persons and upon such terms and conditions (not inconsistent with the provisions of the 2019 Plan), as it may consider appropriate. The Compensation Committee may delegate to one or more of our officers all or part of its authority and duties with respect to awards to individuals who are not subject to Section 16 of the Exchange Act.

Eligibility for Participation. Any of our employees or service providers, including any employees or service providers of our affiliates, and any non-employee member of our board of directors or the boards of directors of our affiliates, is eligible to receive an award under the 2019 Plan. However, ISOs may only be granted to our employees or employees of our affiliates.

Shares Subject to Plan. The maximum number of shares of Ohr common stock that may be issued under the life of the 2019 Plan will be 3,100,000 shares, subject to an "evergreen" provision that will automatically increase the maximum number of shares of our common stock that may be issued under the life of the 2019 Plan on October 1st of each year beginning on October 1, 2019 and continuing through October 1, 2028 by a number of shares equal to 4.0% of the total number of shares of common stock outstanding as of September 30th of the preceding fiscal year, or a lesser number of shares to be determined by our board of directors. Notwithstanding the foregoing, the maximum number of shares of our common stock available for grants of ISOs under the 2019 Plan is 3,100,000 and will not increase.

A share of common stock issued in connection with any award under the 2019 Plan shall reduce the total number of shares of Ohr common stock available for issuance under the 2019 Plan by one; *provided*, *however*, that a share of our common stock covered under a stock-settled SAR shall reduce the total number of shares of common stock available for issuance under the 2019 Plan by one even though the shares of common stock are not actually issued in connection with settlement of the SAR. Except as otherwise provided in the 2019 Plan, any shares of common stock related to an award which terminates by expiration, forfeiture, cancellation or otherwise without issuance of shares of common stock, which is settled in cash in lieu of common stock or which is exchanged, with the Compensation Committee's permission, prior to the issuance of shares of common stock, for awards not involving shares of common stock, shall again be available for issuance under the 2019 Plan. The following shares of common stock, however, may not again be made available for issuance as awards under the 2019 Plan: (i) shares of common stock not issued or delivered as a result of a net settlement of an outstanding award, (ii) shares of common stock tendered or held to pay the exercise price, purchase price or withholding taxes relating to an outstanding award, or (iii) shares of common stock repurchased on the open market with the proceeds of the exercise price of an award.

In any calendar year, no participant may be granted options, SARs, Restricted Stock Awards, RSUs, or any combination thereof that relate to more than 1,000,000 shares of our common stock (subject to adjustment as provided in the 2019 Plan). In any calendar year, no participant may be granted an Incentive Award (i) with reference to a specified dollar limit for more than $3,000,000 and (ii) with reference to a specified number of shares of our common stock for more than 1,000,000 shares of our common stock (subject to adjustment as provided in the 2019 Plan). In any calendar year, no participant who is a member of our board of directors, but is not our employee of or an employee of our affiliate, may be granted options, SARs, Restricted Stock Awards, RSUs, or any combination thereof that relate to more than 300,000 shares of common stock (subject to adjustment as provided in the 2019 Plan). The maximum number of shares of our common stock that may be issued pursuant to awards, the per individual limits on awards and the terms of outstanding awards will be adjusted in a similar manner as the evergreen provisions that apply to the aggregate limits and as the Compensation Committee in its sole discretion determines is equitably required in the event of corporate transactions and other appropriate events.

Options. A stock option entitles the participant to purchase from us a stated number of shares of common stock. The Compensation Committee will determine whether the option is intended to be an ISO or a NQSO and specify the number of shares of common stock subject to the option. In the case of ISOs, the aggregate fair market value (determined as of the date of grant) of common stock with respect to which an ISO may become exercisable for the first time during any calendar year cannot exceed $100,000; and if this limitation is exceeded, the ISOs which cause the limitation to be exceeded will be treated as NQSOs. The exercise price per share of common stock may not be less than the fair market value of our common stock on the date the option is granted. With respect to an ISO granted to a participant who beneficially owns more than 10% of the combined voting power of the Company or any of our affiliates (determined by applying certain attribution rules), the exercise price per share may not be less than 110% of the fair market value of our common stock on the date the option is granted. The exercise price may be paid in cash or, if the agreement so provides, the Compensation Committee may allow a participant to pay all or part of the exercise price by tendering shares of our common stock the participant already owns, through a broker-assisted cashless exercise, by means of "net exercise" procedure, any other specified medium of payment or a combination.

Stock Appreciation Rights. A SAR entitles the participant to receive, upon exercise, the excess of the fair market value on that date of each share of common stock subject to the exercised portion of the SAR over the fair market value of each such share on the date of the grant of the SAR. A SAR can be granted alone or in tandem with an option. A SAR granted in tandem with an option is called a Corresponding SAR and entitles the participant to exercise the option or the SAR at which time the other tandem award expires. The Compensation Committee will specify the number of shares of common stock subject to a SAR and whether the SAR is a Corresponding SAR. No participant may be granted Corresponding SARs in tandem with ISOs which are first exercisable in any calendar year for shares of our common stock having an aggregate fair market value (determined as of the date of grant) that exceeds $100,000; and if this limitation is exceeded the tandem option will be treated as NQSOs. A Corresponding SAR may be exercised only to the extent that the related option is exercisable and the fair market value of the our common stock on the date of exercise exceeds the exercise price of the related option. As set forth in the agreement, the amount payable as a result of the exercise of a SAR may be settled in cash, shares of common stock or a combination of each.

Restricted Stock Awards. A Restricted Stock Award is the grant or sale of shares of our common stock, which may be subject to forfeiture restrictions. The Compensation Committee will prescribe whether the Restricted Stock Award is forfeitable and the conditions to which it is subject. If the participant must pay for a Restricted Stock Award, payment for the award generally shall be made in cash or, if the agreement so provides, by surrendering shares of common stock the participant already owns or any other medium of payment. Prior to vesting or forfeiture, a participant will have all rights of a stockholder with respect to the shares of Ohr common stock underlying the Restricted Stock Award, including the right to receive dividends and vote the underlying shares of our common stock; provided, however, the participant may not transfer the shares. We may retain custody of the certificates evidencing the shares of our common stock until such shares are no longer forfeitable.

RSUs. An RSU entitles the participant to receive shares of common stock when certain conditions are met. The Compensation Committee will prescribe when the RSUs shall become payable. We will pay the participant one share of our common stock for each RSU that becomes earned and payable.

Incentive Awards. An Incentive Award entitles the participant to receive cash or common stock or a combination of each when certain conditions are met. The Compensation Committee will prescribe the terms and conditions of the Incentive Award. As set forth in the participant's agreement, an Incentive Award may be paid in cash, shares of common stock or a combination of each.

Change in Control. In the event of or in anticipation of a "Change in Control" (as defined in the 2019 Plan), the Compensation Committee in its discretion may terminate outstanding awards (i) by giving the participants an opportunity to exercise the awards that are then exercisable and then terminating, without any payment, all awards that have not been exercised (including those that were not then exercisable) or (ii) by paying the participant the value of the awards that are then vested, exercisable or payable without payment for any awards that are not then vested, exercisable or payable or that have no value. Alternatively, the Compensation Committee may take such other action as the Compensation Committee determines to be reasonable under the circumstances to permit the participant to realize the vested value of the award. The Compensation Committee may provide that a participant's outstanding awards become fully exercisable or payable on and after a Change in Control or immediately before the date the awards will be terminated in connection with a Change in Control. Awards will not be terminated to the extent they are to be continued after the Change in Control.

Stockholder Rights. No participant shall have any rights as a stockholder until the award is settled by the issuance of our common stock (other than a Restricted Stock Award or RSUs for which certain stockholder rights may be granted).

Transferability. An award is non-transferable except by will or the laws of descent and distribution, and during the lifetime of the participant to whom the award is granted, the award may only be exercised by, or payable to, the participant. The holder of the transferred award will be bound by the same terms and conditions that governed the award during the period that it was held by the participant.

Maximum Award Period. No award shall be exercisable or become vested or payable more than ten years after the date of grant. An ISO granted to a participant who beneficially owns more than 10% of the combined voting power of Ohr or any affiliate (determined by applying certain attribution rules) or a Corresponding SAR that relates to such an ISO may not be exercisable more than five years after the date of grant.

Compliance With Applicable Law. No award shall be exercisable, vested or payable except in compliance with all applicable federal and state laws and regulations (including, without limitation, tax and securities laws), any listing agreement with any stock exchange to which we are a party, and the rules of all domestic stock exchanges on which our securities may be listed.

Amendment and Termination of Plan. Our board of directors may amend or terminate the 2019 Plan at any time; provided, however, that no amendment may adversely impair the rights of a participant with respect to outstanding awards without the participant's consent. An amendment will be contingent on approval of our stockholders, to the extent required by law, by the rules of any stock exchange on which our securities are then traded or if the amendment would (i) increase the benefits accruing to participants under the 2019 Plan, including without limitation, any amendment to the 2019 Plan or any agreement to permit a repricing or decrease in the exercise price of any outstanding options or SARs, (ii) increase the aggregate number of shares of our common stock that may be issued under the 2019 Plan, or (iii) modify the requirements as to eligibility for participation in the 2019 Plan.

Forfeiture Provisions. Awards do not confer upon any individual any right to continue in the employ or service of the Company or any affiliate. All rights to any award that a participant has will be immediately forfeited if the participant is discharged from employment or service for "Cause" (as defined in the 2019 Plan).

Material U.S. Federal Income Tax Consequences

The following discussion summarizes the material United States federal income tax consequences associated with awards granted under the 2019 Plan to U.S. citizens. The discussion is based on laws, regulations, rulings and court decisions currently in effect, all of which are subject to change.

ISOs. A participant will not recognize taxable income on the grant or exercise of an ISO. A participant will recognize taxable income when he or she disposes of the shares of our common stock acquired under the ISO. If the disposition occurs more than two years after the grant of the ISO and more than one year after its exercise (the "ISO holding period"), the participant will recognize long-term capital gain (or loss) to the extent the amount realized from the disposition exceeds (or is less than) the participant's tax basis in the shares of our common stock. A participant's tax basis in shares of our common stock generally will be the amount the participant paid for the shares.

If our common stock acquired under an ISO is disposed of before the expiration of the ISO holding period described above, the participant will recognize as ordinary income in the year of the disposition the excess of the fair market value of our common stock on the date of exercise of the ISO over the exercise price. Any additional gain will be treated as long-term or short-term capital gain, depending on the length of time the participant held the shares. A special rule applies to such a disposition where the amount realized is less than the fair market value of our common stock on the date of exercise of the ISO. In that case, the ordinary income the participant will recognize will not exceed the excess of the amount realized on the disposition over the exercise price. If the amount realized is less than the exercise price, the participant will recognize a capital loss (long-term if the stock was held more than one year and short-term if held one year or less). A participant will receive different tax treatment if the exercise price is paid by delivery of common stock the participant already owns.

Neither us nor any of our affiliates will be entitled to a federal income tax deduction with respect to the grant or exercise of an ISO. However, in the event a participant disposes of our common stock acquired under an ISO before the expiration of the ISO holding period described above, we or our affiliate will be entitled to a federal income tax deduction equal to the amount of ordinary income the participant recognizes.

NQSOs. A participant will not recognize any taxable income on the grant of a NQSO. On the exercise of a NQSO, the participant will recognize as ordinary income the excess of the fair market value of the Ohr common stock acquired over the exercise price. A participant's tax basis in our common stock is the amount paid plus any amounts included in income on exercise. The participant's holding period for the stock begins on acquisition of the shares. Any gain or loss that a participant realizes on a subsequent disposition of our common stock acquired on the exercise of a NQSO generally will be treated as long-term or short-term capital gain or loss, depending on the length of time the participant held such shares. The amount of the gain (or loss) will equal the amount by which the amount realized on the subsequent disposition exceeds (or is less than) the participant's tax basis in his or her shares. A participant will receive different tax treatment if the exercise price is paid by delivery of Ohr common stock the participant already owns.

The exercise of a NQSO will entitle us or our affiliate to claim a federal income tax deduction equal to the amount of ordinary income the participant recognizes. If the participant is an employee, that ordinary income will constitute wages subject to withholding and employment taxes.

SARs. A participant will not recognize any taxable income at the time the SARs are granted. The participant at the time of receipt will recognize as ordinary income the amount of cash and the fair market value of our common stock that he or she receives. We or our affiliate will be entitled to a federal income tax deduction equal to the amount of ordinary income the participant recognizes. If the participant is an employee, that ordinary income will constitute wages subject to withholding and employment taxes.

Restricted Stock Awards. A participant will recognize ordinary income on account of a Restricted Stock Award on the first day that the shares are either transferable or not subject to a substantial risk of forfeiture. The ordinary income recognized will equal the excess of the fair market value of our common stock on such date over the amount, if any, the participant paid for the Restricted Stock Award. However, even if the shares under a Restricted Stock Award are both nontransferable and subject to a substantial risk of forfeiture, the participant may make a special "83(b) election" within 30 days of the grant date to recognize income, and have his or her tax consequences determined, as of the date the Restricted Stock Award is made. The participant's tax basis in the shares received will equal the income recognized plus the price, if any, paid for the Restricted Stock Award. Any gain (or loss) that a participant realizes upon the sale of any of our common stock acquired pursuant to a Restricted Stock Award will be equal to the amount by which the amount realized on the disposition exceeds (or is less than) the participant's tax basis in the shares and will be treated as long-term (if the shares are held for more than one year) or short-term (if the shares are held for one year or less) capital gain or loss. The participant's holding period for the stock begins on the date the shares are either transferable or not subject to a substantial risk of forfeiture, except that the holding period will begin on the date of grant if the participant makes the special "83(b) election." We or our affiliate will be entitled to a federal income tax deduction equal to the ordinary income the participant recognizes. If the participant is an employee, that ordinary income will constitute wages subject to withholding and employment taxes.

RSUs. The participant will not recognize any taxable income at the time the RSUs are granted. When the terms and conditions to which the RSUs are subject have been satisfied and the RSUs are paid, the participant, at the time of receipt, will recognize as ordinary income the fair market value of our common stock he or she receives. The participant's holding period in our common stock will begin on the date the stock is received. The participant's tax basis in our common stock will equal the amount he or she includes in ordinary income. Any gain or loss that a participant realizes on a subsequent disposition of the shares will be treated as long-term or short-term capital gain or loss, depending on the participant's holding period for the stock (long-term if the shares are held for more than one year; short-term if one year or less). The amount of the gain (or loss) will equal the amount by which the amount realized on the disposition exceeds (or is less than) the participant's tax basis in the Ohr common stock. We or our affiliate will be entitled to a federal income tax deduction equal to the ordinary income the participant recognizes. If the participant is an employee, that ordinary income will constitute wages subject to withholding and employment taxes.

Incentive Awards. A participant will not recognize any taxable income at the time an Incentive Award is granted. When the terms and conditions to which an Incentive Award is subject have been satisfied and the award is paid, the participant, at the time of receipt, will recognize as ordinary income the amount of cash and the fair market value of the Ohr common stock he or she receives. The participant's holding period in any of our common stock received will begin on the date of receipt. The participant's tax basis in our common stock will equal the amount he or she includes in ordinary income with respect to such shares. Any gain or loss that a participant realizes on a subsequent disposition of our common stock will be treated as long-term or short-term capital gain or loss, depending on the participant's holding period for the Ohr common stock (long-term if the shares are held for more than one year; short-term if one year or less). The amount of the gain (or loss) will equal the amount by which the amount realized on the disposition exceeds (or is less than) the participant's tax basis in our common stock. We or our affiliate will be entitled to a federal income tax deduction equal to the amount of ordinary income the participant recognizes. If the participant is an employee, that ordinary income will constitute wages subject to withholding and employment taxes.

Limitation on Deductions. The deduction for a publicly-held corporation for otherwise deductible compensation to a "covered employee" generally is limited to $1 million per year. An individual is a covered employee if he or she is the chief executive officer, chief financial officer, or one of the other three highest compensated officers for the year (other than the chief executive officer or chief financial officer) or ever was a covered employee after December 31, 2016.

Any grant, exercise, vesting or payment of an award may be postponed if we reasonably believes that our or any applicable affiliate's deduction with respect to such award would be limited or eliminated by application of Code Section 162(m) to the extent permitted by Section 409A of the Code; *provided*, *however*, such delay will last only until the earliest date at which we reasonably anticipates the deduction will not be limited or eliminated under Code Section 162(m).

Other Tax Rules. The 2019 Plan is designed to enable the Compensation Committee to structure awards that are intended to not be subject to Code Section 409A, which imposes certain restrictions and requirements on deferred compensation.

NeuBase Therapeutics, Inc. 2018 Equity Incentive Plan

On August 28, 2018, the board of directors of Legacy NeuBase adopted the 2018 Plan, and the Legacy NeuBase stockholders also approved the 2018 Plan on August 28, 2018. Pursuant to the Merger Agreement, at the effective time of the Merger, each outstanding and unexercised option to purchase shares of Legacy NeuBase common stock issued under the 2018 Plan was assumed by us, and became an option to purchase that number of shares of our common stock equal to the product obtained by multiplying (i) the number of shares of Legacy NeuBase common stock that were subject to such option immediately prior to the effective time of the Merger by (ii) the exchange ratio, rounded down to the nearest whole share. The per share exercise price for shares of our common stock issuable upon exercise of each Legacy NeuBase option assumed by us was determined by dividing (a) the per share exercise price of Legacy NeuBase common stock subject to such Legacy NeuBase option, as in effect immediately prior to the effective time of the Merger, by (b) the exchange ratio, rounded up to the nearest whole cent. No new equity awards will be issued under the 2018 Plan. However, the 2018 Plan will continue to govern outstanding awards granted thereunder.

The following is only a summary of the material terms of the 2018 Plan, is not a complete description of all provisions of the 2018 Plan and should be read in conjunction with the 2018 Plan, which is filed as an exhibit to this Annual Report on Form 10-K.

Stock Options and Stock Appreciation Rights. The exercise price of stock options and strike price of stock appreciation rights granted under the 2018 Plan must not be less than 100% of the fair market value of our common stock on the grant date, subject to certain exceptions as set forth in the 2018 Plan. The term of a stock option or stock appreciation rights may not exceed ten years. An ISO may only be granted to our employees or employees of certain of our affiliates, including officers who are employees. An ISO granted to an employee who owns more than 10% of the combined voting power of all of our classes of stock or that of our affiliates must have an exercise price of at least 110% of the fair market value of our common stock on the grant date, and the term of the ISO may not exceed five years from the grant date. To the extent that the aggregate fair market value of shares of our common stock with respect to which ISOs first become exercisable by a participant in any calendar year exceeds $100,000, such excess stock options will be treated as Non-ISOs. The methods of payment of the exercise price of a stock option may include, among other things, cash, other shares (subject to certain conditions), "net exercise" (for Non-ISOs), cashless exercise, deferred payment or similar arrangements, as well as other forms of legal consideration that may be acceptable to our board of directors and specified in the applicable stock option award agreement. To exercise any outstanding stock appreciation right, the participant must provide written notice of exercise to us. The appreciation distribution payable on the exercise of a stock appreciation right may be paid in our common stock, cash, a combination of our common stock and cash or in any other form of consideration determined by our board of directors and contained in the award agreement. Our board of directors may establish and set forth in the applicable stock option award agreement or other agreement the terms and conditions on which a stock option or stock appreciation right will remain exercisable, if at all, following termination of a participant's service. Unless an award agreement provides otherwise: (1) if termination is due to death, the stock option or stock appreciation right will remain exercisable for six months after such termination of service; (2) if termination is due to disability, the stock option or stock appreciation right will remain exercisable for six months after such termination of service; and (3) if the termination is due to reasons other than for death or disability, the stock option or stock appreciation right generally will remain exercisable for thirty days following termination of service. If a participant is not entitled to exercise a stock option or stock appreciation right at the date of termination of service, or if the participant does not exercise the stock option or stock appreciation right to the extent so entitled within the time specified in the applicable stock option award agreement or other agreement or in the 2018 Plan, the stock option or stock appreciation right will terminate.

Restricted Stock Awards. Each restricted stock award agreement will be in the form and contain such terms and conditions as our board of directors deems appropriate. At our board of directors' election, shares of our common stock may be (1) held in book entry form until any restrictions relating to the restricted stock award lapse or (2) evidenced by a certificate that is held in a form and manner determined by our board of directors. The methods of payment of consideration for a restricted stock award may include any form of legal consideration that may be acceptable to our board of directors and permissible under applicable law including the provision of services. Shares of our common stock awarded under a restricted stock award agreement may be subject to forfeiture in accordance with a vesting schedule. Following termination of a participant's service, we may receive through a forfeiture condition or repurchase right, any or all of the shares of our common stock held by the participant as of the date of termination under the terms of the restricted stock award agreement. Dividends paid on restricted common stock may be subject to the same vesting and forfeiture restrictions that apply to the shares of our common stock under the restricted stock award.

Restricted Stock Unit Awards. Each restricted stock unit award agreement will be in the form and contain such terms and conditions as our board of directors deems appropriate. Payment for each share of our common stock subject to a restricted stock unit award may be in any form of legal consideration that may be acceptable to our board of directors and permissible under applicable law including the provision of services. Our board of directors may, in its sole discretion, impose restrictions on or conditions to the vesting of a restricted stock unit award. Each restricted stock unit award may be settled by delivery of our common stock, the cash value of our common stock, a combination of our common stock and cash or in any other form of consideration determined by our board of directors and contained in the award agreement. Our board of directors may, at the time of grant, impose restrictions or conditions on a restricted stock unit award that delay the delivery of our common stock subject to such restricted stock unit award to a time after such restricted stock unit award vests. Unless an award agreement provides otherwise, any unvested portion of a restricted stock unit award will be forfeited upon a participant's termination of service.

Taxes. Prior to the delivery of cash or shares in settlement or exercise of any award, we may withhold and/or require the holder to remit to us amount sufficient to satisfy all taxes required to be withheld under applicable laws.

Non-Transferability. Unless our board of directors provides otherwise in an award agreement, or unless transferred pursuant to a will or by the laws of descent and distribution, the 2018 Plan generally does not allow for the transfer of awards and only the participant who is granted an award may exercise an award during his or her lifetime.

Certain Adjustments. In the event of certain changes in our capitalization, such as any dividend or other distribution (whether in the form of cash, our common stock, other securities or other property), stock splits, reverse stock splits, combinations, recapitalizations or reorganizations with respect to our common stock, or mergers, consolidations, changes in organization form or other increases or decreases in the number of issued shares of our common stock effected without receipt or payment of consideration by us, our board of directors will proportionally adjust the number and price of shares covered by each outstanding award and the total number of shares authorized for issuance under the 2018 Plan. Unless our board of directors provides otherwise in an award agreement, in the event of any proposed dissolution or liquidation of us, other than as part of a corporate transaction, we will notify each participant as soon as practicable and all awards will terminate immediately prior to the consummation of such proposed corporate transaction.

Corporate Transaction. In the event of a corporate transaction involving us, our board of directors has the discretion to take one or more of the following actions with respect to any or all awards: (1) arrange for the surviving company or acquiring company to assume or continue the stock awards or substitute a substantially equivalent stock award; (2) upon to notice to the holder, provide for the termination of such holder's awards upon or immediately prior to the transaction; (3) accelerate the vesting, in whole or in part, of the stock awards (and, if applicable, the time at which the stock awards may be exercised) to a date prior to the effective time of such corporate transaction as our board of directors will determine at or prior to the effective time of the corporate transaction; (4) arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by us with respect to the stock awards; (5) cancel or arrange for the cancellation of the stock award in exchange for a payment cash and/or property equal to the excess, if any, of (A) the amount the participant would have received upon the exercise or settlement of the stock award immediately prior to the effective time of the corporate transaction, over (B) any exercise or strike price payable by such holder in connection with such exercise (and if as of the date of the occurrence of the corporate transaction our board of directors determines in good faith that no amount would have been attained upon the exercise or settlement of such award, then such award may be terminated without payment); (6) the replacement of such award with other rights or property selected by our board of directors in its sole discretion; or (7) any combination of the above. Our board of directors is not required to take the same action or actions with respect to all awards granted under the 2018 Plan, or portions thereof, or with respect to all participants, and may take any of the different actions described above with respect to the vested and unvested portions of any award. In the event that a successor corporation does not assume or substitute for the award, the award shall become fully vested (with any performance-based vesting deemed attained at 100% of target levels and other terms and conditions met). A corporate transaction means, (i) a merger, following which we are not the surviving company, (ii) any one person or more than one person acting as group acquires ownership of our stock that, together with any stock held by such person(s), constitutes more than 50% of the voting power of our stock, except that any change in the ownership of our stock as a result of a private financing that is approved by our board of directors; (iii) if we have a class of securities registered pursuant to Section 12 of the Exchange Act, a majority of members of our board of directors is replaced during any twelve month period by directors who appointment or election is not endorsed by a majority of members of our board of directors prior to the date of appointment or election; or (iv) any person acquires within any twelve month period our assets having a total gross fair market value of at least 50% of the total fair market value of our assets.

Amendment; Termination. The 2018 Plan may be amended or terminated by our board of directors as it deems advisable; however, stockholder approval is required for any change that that (1) materially increases the number of shares of our common stock available for issuance under the 2018 Plan, or (2) materially expands the class of individuals eligible to receive awards under the 2018 Plan. The 2018 Plan will terminate on July 8, 2026, if not sooner terminated by NeuBase's board of directors.

Ohr Pharmaceutical, Inc. 2016 Consolidated Stock Incentive Plan

On January 7, 2016, our board of directors adopted the 2016 Plan and our shareholders approved the plan on March 17, 2016 to assist us in recruiting and retaining individuals with ability and initiative by enabling them to receive awards and participate in our future success by associating their interests with those of us and our stockholders. The 2016 Plan is intended to permit the grant of stock options (both ISOs and NQSOs), SARs, Restricted Stock Awards, RSUs and Incentive Awards. The following is only a summary of the material terms of the 2016 Plan, is not a complete description of all provisions of the 2016 Plan and should be read in conjunction with the 2016 Plan, which is filed as an exhibit to this Annual Report on Form 10-K.

Prior Plans. We previously maintained each of the 2014 Plan and the 2009 Plan. The 2016 Plan is intended to consolidate the 2014 Plan and the 2009 Plan into a new plan, with an aggregate number of shares available for issuance under the 2016 Plan as set forth below under "- Shares Subject to Plan." For options and Restricted Stock Awards granted under the 2014 Plan and the 2009 Plan prior to January 7, 2016, the terms and conditions of the 2014 Plan and the 2009 Plan and the applicable award agreements will control, except that the our Compensation Committee, in its discretion may allow a participant to pay all or part of the option price (i) by surrendering shares of common stock to us that the participant already owns and, if necessary to avoid adverse accounting consequences, has held for at least six months; (ii) by a cashless exercise through a broker; (iii) by means of a "net exercise" procedure, (iv) by such other medium of payment as the Compensation Committee in its discretion shall authorize or (v) by any combination of the aforementioned methods of payment. If shares of common stock are used to pay all or part of the option price, the sum of the cash and cash equivalent and the fair market value (determined as of the day preceding the date of exercise) of the shares surrendered shall equal the option price of the shares for which the option is being exercised.

Written Agreements. All awards granted under the 2016 Plan will be governed by separate written agreements between us and the participants. The written agreements will specify when the award may become vested, exercisable or payable, as well as other terms and conditions that may apply to the award. No right or interest of a participant in any award will be subject to any lien, obligation or liability of the participant. The laws of the State of Delaware govern the 2016 Plan.

No awards may be granted after January 7, 2026, the date which is 10 years after the adoption of the 2016 Plan by the board of directors.

Tax Treatment. It is intended that awards granted under the 2016 Plan shall be exempt from treatment as "deferred compensation" subject to Section 409A of the Internal Revenue Code of 1986 (and any amendments thereto) (the "Code").

Administration. We bear all expenses of administering the 2016 Plan. The Compensation Committee administers the 2016 Plan. The Compensation Committee has the authority to grant awards to such persons and upon such terms and conditions (not inconsistent with the provisions of the 2016 Plan), as it may consider appropriate. The Compensation Committee may delegate to one or more of our officers all or part of its authority and duties with respect to awards to individuals who are not subject to Section 16 of the Exchange Act.

Eligibility for Participation. Any of our employees or service providers, including any employees or service providers of our affiliates, and any non-employee member of our board of directors or the boards of directors of our affiliates, is eligible to receive an award under the 2016 Plan. However, ISOs may only be granted to our employees or employees of our affiliates.

Shares Subject to Plan. The maximum number of shares of our common stock that may be issued under the life of the 2016 Plan pursuant to awards will be (a) 291,667 shares minus (b) the number of shares of our common stock that previously have been issued pursuant to the exercise of options under the 2009 Plan or 2014 Plan or the number of shares of restricted stock granted under the 2014 Plan and the 2009 Plan that, as of December 28, 2018 are no longer subject to a substantial risk of forfeiture. One hundred percent (100%) of such shares may be issued pursuant to options (including ISOs), SARs, Restricted Stock Awards, RSUs or Incentive Awards or any combination of awards. Of the 291,667 shares, 16,667 previously were authorized under the 2009 Plan and 137,500 previously were authorized under the 2014 Plan.

Shares of common stock covered by an award shall only be counted as issued to the extent they are actually issued. A share of common stock issued in connection with any award under the 2016 Plan shall reduce the total number of shares of our common stock available for issuance under the 2016 Plan by one; provided, however, that a share of our common stock covered under a stock-settled SAR shall reduce the total number of shares of common stock available for issuance under the 2016 Plan by one even though the shares of common stock are not actually issued in connection with settlement of the SAR. Except as otherwise provided in the 2016 Plan, any shares of common stock related to an award which terminates by expiration, forfeiture, cancellation or otherwise without issuance of shares of common stock, which is settled in cash in lieu of common stock or which is exchanged, with the Compensation Committee's permission, prior to the issuance of shares of common stock, for awards not involving shares of common stock, shall again be available for issuance under the 2016 Plan. The following shares of common stock, however, may not again be made available for issuance as awards under the 2016 Plan: (i) shares of common stock not issued or delivered as a result of a net settlement of an outstanding award, (ii) shares of common stock tendered or held to pay the exercise price, purchase price or withholding taxes relating to an outstanding award, or (iii) shares of common stock repurchased on the open market with the proceeds of the exercise price of an award.

In any calendar year, no participant may be granted options, SARs, Restricted Stock Awards, RSUs, or any combination thereof that relate to more than 500,000 shares of our common stock (subject to adjustment as provided in the 2016 Plan). In any calendar year, no participant may be granted an Incentive Award (i) with reference to a specified dollar limit for more than $3,000,000 million and (ii) with reference to a specified number of shares of common stock for more than 500,000 shares of common stock (subject to adjustment as provided in the 2016 Plan). The maximum number of shares of our common stock that may be issued pursuant to awards, the per individual limits on awards and the terms of outstanding awards will be adjusted as the Compensation Committee in its sole discretion determines is equitably required in the event of corporate transactions and other appropriate events.

Options. A stock option entitles the participant to purchase from us a stated number of shares of common stock. The Compensation Committee will determine whether the option is intended to be an ISO or a NQSO and specify the number of shares of common stock subject to the option. In the case of ISOs, the aggregate fair market value (determined as of the date of grant) of common stock with respect to which an ISO may become exercisable for the first time during any calendar year cannot exceed $100,000; and if this limitation is exceeded, the ISOs which cause the limitation to be exceeded will be treated as NQSOs. The exercise price per share of common stock may not be less than the fair market value of our common stock on the date the option is granted. With respect to an ISO granted to a participant who beneficially owns more than 10% of the combined voting power of the Company or any of our affiliate (determined by applying certain attribution rules), the exercise price per share may not be less than 110% of the fair market value of our common stock on the date the option is granted. The exercise price may be paid in cash or, if the agreement so provides, the Compensation Committee may allow a participant to pay all or part of the exercise price by tendering shares of our common stock the participant already owns, through a broker-assisted cashless exercise, by means of "net exercise" procedure, any other specified medium of payment or a combination.

Stock Appreciation Rights. A SAR entitles the participant to receive, upon exercise, the excess of the fair market value on that date of each share of common stock subject to the exercised portion of the SAR over the fair market value of each such share on the date of the grant of the SAR. A SAR can be granted alone or in tandem with an option. A SAR granted in tandem with an option is called a Corresponding SAR and entitles the participant to exercise the option or the SAR at which time the other tandem award expires. The Compensation Committee will specify the number of shares of common stock subject to a SAR and whether the SAR is a Corresponding SAR. No participant may be granted Corresponding SARs in tandem with ISOs which are first exercisable in any calendar year for shares of common stock having an aggregate fair market value (determined as of the date of grant) that exceeds $100,000; and if this limitation is exceeded the tandem option will be treated as NQSOs. A Corresponding SAR may be exercised only to the extent that the related option is exercisable and the fair market value of the common stock on the date of exercise exceeds the exercise price of the related option. As set forth in the agreement, the amount payable as a result of the exercise of a SAR may be settled in cash, shares of common stock or a combination of each.

Restricted Stock Awards. A Restricted Stock Award is the grant or sale of shares of our common stock, which may be subject to forfeiture restrictions. The Compensation Committee will prescribe whether the Restricted Stock Award is forfeitable and the conditions to which it is subject. If the participant must pay for a Restricted Stock Award, payment for the award generally shall be made in cash or, if the agreement so provides, by surrendering shares of common stock the participant already owns or any other medium of payment. Prior to vesting or forfeiture, a participant will have all rights of a shareholder with respect to the shares underlying the Restricted Stock Award, including the right to receive dividends and vote the underlying shares; provided, however, the participant may not transfer the shares. We may retain custody of the certificates evidencing the shares or our common stock until such shares are no longer forfeitable.

RSUs. An RSU entitles the participant to receive shares of common stock when certain conditions are met. The Compensation Committee will prescribe when the RSUs shall become payable. We will pay the participant one share of our common stock for each RSU that becomes earned and payable.

Incentive Awards. An Incentive Award entitles the participant to receive cash or common stock or a combination of each when certain conditions are met. The Compensation Committee will prescribe the terms and conditions of the Incentive Award. As set forth in the participant's agreement, an Incentive Award may be paid in cash, shares of common stock or a combination of each.

Performance Objectives. The Compensation Committee has discretion to establish objectively-determinable performance conditions for when awards will become vested, exercisable and payable. Objectively-determinable performance conditions are performance conditions (i) that are established in writing (a) at the time of grant (b) no later than the earlier of (x) 90 days after the beginning of the period of service to which they relate and (y) before the lapse of 25% of the period of service to which they relate; (ii) that are uncertain of achievement at the time they are established; and (iii) the achievement of which is determinable by a third party with knowledge of the relevant facts. These performance conditions may include any or any combination of the following: (a) gross, operating or net earnings before or after taxes; (b) return on equity; (c) return on capital; (d) return on sales; (e) return on investments; (f) return on assets or net assets; (g) earnings per share; (h) cash flow per share; (i) book value per share; (j) gross margin; (k) customers; (l) cash flow or cash flow from operations; (m) fair market value of us or any affiliate or shares of Common Stock; (n) share price or total shareholder return; (o) market share; (p) level of expenses or other costs; (q) gross, operating or net revenue; (r) earnings before interest and taxes; (s) adjusted earnings before interest and taxes; (t) profitability; (u) earnings before interest, taxes, depreciation and amortization; (v) adjusted earnings before interest, taxes, depreciation and amortization; (w) adjusted earnings before interest, taxes, depreciation and amortization less capital expenditures; (x) research and development milestones; (y) business development objectives, partnerships and other collaborations; or (z) peer group comparisons of any of the aforementioned performance conditions. Performance conditions may be related to a specific customer or group of customers or geographic region. The form of the performance conditions also may be measured on a Company, affiliate, division, business unit, service line, segment or geographic basis or a combination thereof. Performance goals may reflect absolute entity performance or a relative comparison of entity performance to the performance of a peer group of entities or other external measure of the selected performance conditions. Profits, earnings and revenues used for any performance condition measurement may exclude any extraordinary or nonrecurring items. The performance conditions may, but need not, be based upon an increase or positive result under the aforementioned performance criteria and could include, for example and not by way of limitation, maintaining the status quo or limiting the economic losses (measured, in each case, by reference to the specific business criteria). An award that is intended to become exercisable, vested or payable on the achievement of performance conditions means that the award will not become exercisable, vested or payable solely on mere continued employment or service. However, such an award, in addition to performance conditions, may be subject to continued employment or service by the participant. Additionally, the vesting, exercise or payment of an award can be conditioned on mere continued employment or service if it is not intended to qualify as qualified performance-based compensation under Section 162(m) of the Code.

Change in Control. In the event of or in anticipation of a "Change in Control" (as defined in the 2016 Plan), the Compensation Committee in its discretion may terminate outstanding awards (i) by giving the participants an opportunity to exercise the awards that are then exercisable and then terminating, without any payment, all awards that have not been exercised (including those that were not then exercisable) or (ii) by paying the participant the value of the awards that are then vested, exercisable or payable without payment for any awards that are not then vested, exercisable or payable or that have no value. Alternatively, the Compensation Committee may take such other action as the Compensation Committee determines to be reasonable under the circumstances to permit the participant to realize the vested value of the award. The Compensation Committee may provide that a participant's outstanding awards become fully exercisable or payable on and after a Change in Control or immediately before the date the awards will be terminated in connection with a Change in Control. Awards will not be terminated to the extent they are to be continued after the Change in Control.

Stockholder Rights. No participant shall have any rights as a shareholder of us until the award is settled by the issuance of our common stock (other than a Restricted Stock Award or RSUs for which certain shareholder rights may be granted).

Transferability. An award is non-transferable except by will or the laws of descent and distribution, and during the lifetime of the participant to whom the award is granted, the award may only be exercised by, or payable to, the participant. The holder of the transferred award will be bound by the same terms and conditions that governed the award during the period that it was held by the participant.

Maximum Award Period. No award shall be exercisable or become vested or payable more than ten years after the date of grant. An ISO granted to a participant who beneficially owns more than 10% of the combined voting power of us or any affiliate (determined by applying certain attribution rules) or a Corresponding SAR that relates to such an ISO may not be exercisable more than five years after the date of grant.

Compliance With Applicable Law. No award shall be exercisable, vested or payable except in compliance with all applicable federal and state laws and regulations (including, without limitation, tax and securities laws), any listing agreement with any stock exchange to which we are a party, and the rules of all domestic stock exchanges on which our shares may be listed.

Amendment and Termination of Plan. Our board of directors may amend or terminate the 2016 Plan at any time; provided, however, that no amendment may adversely impair the rights of a participant with respect to outstanding awards without the participant's consent. An amendment will be contingent on approval of our shareholders, to the extent required by law, by the rules of any stock exchange on which our securities are then traded or if the amendment would (i) increase the benefits accruing to participants under the 2016 Plan, including without limitation, any amendment to the 2016 Plan or any agreement to permit a repricing or decrease in the exercise price of any outstanding options or SARs, (ii) increase the aggregate number of shares of our common stock that may be issued under the 2016 Plan, (iii) modify the requirements as to eligibility for participation in the 2016 Plan or (iv) change the stated performance conditions for qualified performance-based compensation under Section 162(m) of the Code. Additionally, to the extent the board of directors deems necessary for the 2016 Plan to continue to grant awards that are intended to comply with the performance-based exception to the deduction limits of Code Section 162(m), the board of directors will submit the material terms of the stated performance conditions to our shareholders for approval no later than the first shareholder meeting that occurs in the fifth year following the year in which the shareholders previously approved the material terms of the performance goals.

Notwithstanding any other provision of the 2016 Plan, the Compensation Committee may amend any outstanding award without participant's consent if, as determined by the Compensation Committee in its sole discretion, such amendment is required either to (i) confirm exemption from Section 409A of the Code, (ii) comply with Section 409A of the Code or (iii) prevent the Participant from being subject to any tax or penalty under Section 409A of the Code.

Forfeiture Provisions. Awards do not confer upon any individual any right to continue in the employ or service of us or any affiliate. All rights to any award that a participant has will be immediately forfeited if the participant is discharged from employment or service for "Cause" (as defined in the 2016 Plan).

Material U.S. Federal Income Tax Consequences

The following discussion summarizes the material United States federal income tax consequences associated with awards granted under the 2016 Plan to U.S. citizens. The discussion is based on laws, regulations, rulings and court decisions currently in effect, all of which are subject to change.

ISOs. A participant will not recognize taxable income on the grant or exercise of an ISO. A participant will recognize taxable income when he or she disposes of the shares of our common stock acquired under the ISO. If the disposition occurs after the ISO holding period, the participant will recognize long-term capital gain (or loss) to the extent the amount realized from the disposition exceeds (or is less than) the participant's tax basis in the shares of our common stock. A participant's tax basis in shares of the our common stock generally will be the amount the participant paid for the shares.

If our common stock acquired under an ISO is disposed of before the expiration of the ISO holding period described above, the participant will recognize as ordinary income in the year of the disposition the excess of the fair market value of our common stock on the date of exercise of the ISO over the exercise price. Any additional gain will be treated as long-term or short-term capital gain, depending on the length of time the participant held the shares. A special rule applies to such a disposition where the amount realized is less than the fair market value of our common stock on the date of exercise of the ISO. In that case, the ordinary income the participant will recognize will not exceed the excess of the amount realized on the disposition over the exercise price. If the amount realized is less than the exercise price, the participant will recognize a capital loss (long-term if the stock was held more than one year and short-term if held one year or less). A participant will receive different tax treatment if the exercise price is paid by delivery of our common stock the participant already owns.

Neither us nor any of our affiliates will be entitled to a federal income tax deduction with respect to the grant or exercise of an ISO. However, in the event a participant disposes of our common stock acquired under an ISO before the expiration of the ISO holding period described above, we or our affiliate will be entitled to a federal income tax deduction equal to the amount of ordinary income the participant recognizes.

NQSOs. A participant will not recognize any taxable income on the grant of a NQSO. On the exercise of a NQSO, the participant will recognize as ordinary income the excess of the fair market value of our common stock acquired over the exercise price. A participant's tax basis in our common stock is the amount paid plus any amounts included in income on exercise. The participant's holding period for the stock begins on acquisition of the shares. Any gain or loss that a participant realizes on a subsequent disposition of our common stock acquired on the exercise of a NQSO generally will be treated as long-term or short-term capital gain or loss, depending on the length of time the participant held such shares. The amount of the gain (or loss) will equal the amount by which the amount realized on the subsequent disposition exceeds (or is less than) the participant's tax basis in his or her shares. A participant will receive different tax treatment if the exercise price is paid by delivery of our common stock the participant already owns.

The exercise of a NQSO will entitle us or our affiliate to claim a federal income tax deduction equal to the amount of ordinary income the participant recognizes. If the participant is an employee, that ordinary income will constitute wages subject to withholding and employment taxes.

SARs. A participant will not recognize any taxable income at the time the SARs are granted. The participant at the time of receipt will recognize as ordinary income the amount of cash and the fair market value of our common stock that he or she receives. We or our affiliate will be entitled to a federal income tax deduction equal to the amount of ordinary income the participant recognizes. If the participant is an employee, that ordinary income will constitute wages subject to withholding and employment taxes.

Restricted Stock Awards. A participant will recognize ordinary income on account of a Restricted Stock Award on the first day that the shares are either transferable or not subject to a substantial risk of forfeiture. The ordinary income recognized will equal the excess of the fair market value of our common stock on such date over the amount, if any, the participant paid for the Restricted Stock Award. However, even if the shares under a Restricted Stock Award are both nontransferable and subject to a substantial risk of forfeiture, the participant may make a special "83(b) election" within 30 days of the grant date to recognize income, and have his or her tax consequences determined, as of the date the Restricted Stock Award is made. The participant's tax basis in the shares received will equal the income recognized plus the price, if any, paid for the Restricted Stock Award. Any gain (or loss) that a participant realizes upon the sale of any common stock acquired pursuant to a Restricted Stock Award will be equal to the amount by which the amount realized on the disposition exceeds (or is less than) the participant's tax basis in the shares and will be treated as long-term (if the shares are held for more than one year) or short-term (if the shares are held for one year or less) capital gain or loss. The participant's holding period for the stock begins on the date the shares are either transferable or not subject to a substantial risk of forfeiture, except that the holding period will begin on the date of grant if the participant makes the special "83(b) election." We or our affiliate will be entitled to a federal income tax deduction equal to the ordinary income the participant recognizes. If the participant is an employee, that ordinary income will constitute wages subject to withholding and employment taxes.

RSUs. The participant will not recognize any taxable income at the time the RSUs are granted. When the terms and conditions to which the RSUs are subject have been satisfied and the RSUs are paid, the participant, at the time of receipt, will recognize as ordinary income the fair market value of our common stock he or she receives. The participant's holding period in our common stock will begin on the date the stock is received. The participant's tax basis in the common stock will equal the amount he or she includes in ordinary income. Any gain or loss that a participant realizes on a subsequent disposition of the shares will be treated as long-term or short-term capital gain or loss, depending on the participant's holding period for the stock (long-term if the shares are held for more than one year; short-term if one year or less). The amount of the gain (or loss) will equal the amount by which the amount realized on the disposition exceeds (or is less than) the participant's tax basis in our common stock. We or our affiliate will be entitled to a federal income tax deduction equal to the ordinary income the participant recognizes. If the participant is an employee, that ordinary income will constitute wages subject to withholding and employment taxes.

Incentive Awards. A participant will not recognize any taxable income at the time an Incentive Award is granted. When the terms and conditions to which an Incentive Award is subject have been satisfied and the award is paid, the participant, at the time of receipt, will recognize as ordinary income the amount of cash and the fair market value of our common stock he or she receives. The participant's holding period in any of our common stock received will begin on the date of receipt. The participant's tax basis in our common stock will equal the amount he or she includes in ordinary income with respect to such shares. Any gain or loss that a participant realizes on a subsequent disposition of our common stock will be treated as long-term or short-term capital gain or loss, depending on the participant's holding period for our common stock (long-term if the shares are held for more than one year; short-term if one year or less). The amount of the gain (or loss) will equal the amount by which the amount realized on the disposition exceeds (or is less than) the participant's tax basis in our common stock. We or our affiliate will be entitled to a federal income tax deduction equal to the amount of ordinary income the participant recognizes. If the participant is an employee, that ordinary income will constitute wages subject to withholding and employment taxes.

Limitation on Deductions. The deduction for a publicly-held corporation for otherwise deductible compensation to a "covered employee" generally is limited to $1 million per year. An individual is a covered employee if he or she is the chief executive officer or one of the other three highest compensated officers for the year (other than the chief executive officer or chief financial officer). The $1 million limit does not apply to compensation payable solely because of the attainment of performance conditions that meet the requirements set forth in Section 162(m) of the Code and the regulations thereunder. Compensation is considered performance-based only if (a) it is paid solely on the achievement of one or more performance conditions; (b) two or more "outside directors" set the performance conditions; (c) before payment, the material terms under which the compensation is to be paid, including the performance conditions, are disclosed to, and approved by, the shareholders; and (d) before payment, two or more "outside directors" certify in writing that the performance conditions have been met. The 2016 Plan has been designed to enable the Compensation Committee to structure awards that are intended to meet the requirements for qualified performance-based compensation that would not be subject to the $1 million per year deduction limit under Section 162(m) of the Code.

Any grant, exercise, vesting or payment of an award may be postponed if we reasonably believes that our or any applicable affiliate's deduction with respect to such award would be limited or eliminated by application of Section 162(m) of the Code to the extent permitted by Section 409A of the Code; provided, however, such delay will last only until the earliest date at which we reasonably anticipates the deduction will not be limited or eliminated under Section 162(m) of the Code.

Other Tax Rules. The 2016 Plan is designed to enable the Compensation Committee to structure awards that are intended to not be subject to Code Section 409A, which imposes certain restrictions and requirements on deferred compensation.

Ohr Pharmaceutical, Inc. 2014 Stock Incentive Plan

The 2014 Plan was first adopted by our board of directors on January 31, 2014, and by the shareholders on March 31, 2014, as amended by the board of directors on January 6, 2015, and by the shareholders on March 10, 2015.

The 2014 Plan is designed to advance our interests by enhancing our ability to attract and retain employees and others in a position to make significant contributions to our success through ownership of shares of common stock. The 2014 Plan provides for the grant of ISOs, NQSOs, restricted stock, and combinations of the above. Awards under the 2014 Plan may also include provision for payment of dividend equivalents with respect to the shares subject to the award.

The 2014 Plan is administered by our Compensation Committee. All employees of us and any of our subsidiaries and other persons or entities (including non-employee directors of us and our subsidiaries) who, in the opinion of the board of directors, are in a position to make a significant contribution to the success of the us or our subsidiaries are eligible to participate in the 2014 Plan.

As described above, the 2016 Plan is intended to consolidate the 2014 Plan and the 2009 Plan into a new plan. For options and Restricted Stock Awards granted under the 2014 Plan prior to January 7, 2016, the terms and conditions of the 2014 Plan and the applicable award agreements will control, except that the our Compensation Committee, in its discretion may allow a participant to pay all or part of the option price (i) by surrendering shares of common stock to us that the participant already owns and, if necessary to avoid adverse accounting consequences, has held for at least six months; (ii) by a cashless exercise through a broker; (iii) by means of a "net exercise" procedure, (iv) by such other medium of payment as the Compensation Committee in its discretion shall authorize or (v) by any combination of the aforementioned methods of payment. If shares of common stock are used to pay all or part of the option price, the sum of the cash and cash equivalent and the fair market value (determined as of the day preceding the date of exercise) of the shares surrendered shall equal the option price of the shares for which the option is being exercised.

The following is only a summary of the material terms of the 2014 Plan, is not a complete description of all provisions of the 2014 Plan and should be read in conjunction with the 2014 Plan, which is filed as an exhibit to this Annual Report on Form 10-K.

Summary of the 2014 Plan

The exercise price of an ISO granted under the 2014 Plan may not be less than 100% (110% in the case of 10% stockholders) of the fair market value of the common stock at the time of grant. The exercise price of a NQSO granted under the 2014 Plan is determined by the board of directors. The term of each option may be set by the board of directors but cannot exceed ten years from grant (five years from grant in the case of an ISO granted to a 10% stockholder), and each option will be exercisable at such time or times as the board of directors specifies. The option price may be paid in cash or check acceptable to us or, if permitted by the board of directors and subject to certain additional limitations, by tendering shares of common stock, by using a promissory note, by delivering to us an unconditional and irrevocable undertaking by a broker promptly to deliver sufficient funds to pay the exercise price, or a combination of the foregoing.

Except as otherwise provided by the board of directors, if a participant dies, options held by such participant immediately prior to death, to the extent then exercisable, may be exercised by the participant's executor, administrator or transferee during a period of one year following such death (or for the remainder of their original term, if less). Except as otherwise determined by board of directors, options not exercisable at a participant's death terminate. Outstanding awards of restricted common stock must be transferred to us upon a participant's death except as otherwise determined by the board of directors.

In the case of termination of a participant's association with us for any reason other than death, options remain exercisable, to the extent they were exercisable immediately prior to termination, for 30 days (or for the remainder of their original term, if less), and shares of restricted common stock must be resold to us, unless otherwise determined by the board of directors. If any such association is terminated due to the participant's discharge for cause which, in the opinion of the board of directors, casts such discredit on the participant as to justify immediate termination of any award under the 2014 Plan, such participant's options may be terminated immediately.

In the event of a consolidation or merger in which we are not the surviving corporation or which results in the acquisition of substantially all of our outstanding common stock by a single person or entity or by a group of persons and/or entities acting in concert or in the event of the sale or transfer of substantially all of our assets, the board of directors may determine that (i) each outstanding option will become immediately exercisable unless otherwise provided at the time of grant, and (ii) each outstanding share of restricted common stock will immediately become free of all restrictions and conditions. The board of directors may also arrange to have the surviving or acquiring corporation or affiliate assume any award held by a participant or grant a replacement award. If the optionee is terminated after a change in control by us without cause, or in the case of certain officers designated from time to time by the board of directors resigns under certain circumstances, within two years following the change in control, all unvested options will vest and all options will be exercisable for the shorter of four years or their original duration and all other awards will vest. If the option committee makes no such determination, outstanding awards to the extent not fully vested will be forfeited.

Material U.S. Federal Income Tax Consequences

The following discussion summarizes the principal United States federal income tax consequences associated with awards granted under the 2014 Plan to U.S. citizens. The discussion is based on laws, regulations, rulings and court decisions currently in effect, all of which are subject to change.

ISOs. A participant will not recognize taxable income on the grant or exercise of an ISO. A participant will recognize taxable income when he or she disposes of the shares of our common stock acquired under the ISO. If the disposition occurs after the ISO holding period, the participant will recognize long-term capital gain (or loss) to the extent the amount realized from the disposition exceeds (or is less than) the participant's tax basis in the shares of our common stock. A participant's tax basis in shares of our common stock generally will be the amount the participant paid for the shares.

If our common stock acquired under an ISO is disposed of before the expiration of the ISO holding period described above, the participant will recognize as ordinary income in the year of the disposition the excess of the fair market value of our common stock on the date of exercise of the ISO over the exercise price. Any additional gain will be treated as long-term or short-term capital gain, depending on the length of time the participant held the shares. A special rule applies to such a disposition where the amount realized is less than the fair market value of our common stock on the date of exercise of the ISO. In that case, the ordinary income the participant will recognize will not exceed the excess of the amount realized on the disposition over the exercise price. If the amount realized is less than the exercise price, the participant will recognize a capital loss (long-term if the stock was held more than one year and short-term if held one year or less). A participant will receive different tax treatment if the exercise price is paid by delivery of common stock the participant already owns.

Neither us nor any of our affiliates will be entitled to a federal income tax deduction with respect to the grant or exercise of an ISO. However, in the event a participant disposes of our common stock acquired under an ISO before the expiration of the ISO holding period described above, we or our affiliate will be entitled to a federal income tax deduction equal to the amount of ordinary income the participant recognizes.

NQSOs. A participant will not recognize any taxable income on the grant of a NQSO. On the exercise of a NQSO, the participant will recognize as ordinary income the excess of the fair market value of the Ohr common stock acquired over the exercise price. A participant's tax basis in our common stock is the amount paid plus any amounts included in income on exercise. The participant's holding period for the stock begins on acquisition of the shares. Any gain or loss that a participant realizes on a subsequent disposition of our common stock acquired on the exercise of a NQSO generally will be treated as long-term or short-term capital gain or loss, depending on the length of time the participant held such shares. The amount of the gain (or loss) will equal the amount by which the amount realized on the subsequent disposition exceeds (or is less than) the participant's tax basis in his or her shares. A participant will receive different tax treatment if the exercise price is paid by delivery of Ohr common stock the participant already owns.

The exercise of a NQSO will entitle us or our affiliate to claim a federal income tax deduction equal to the amount of ordinary income the participant recognizes. If the participant is an employee, that ordinary income will constitute wages subject to withholding and employment taxes.

Restricted Stock Awards. A participant will recognize ordinary income on account of a Restricted Stock Award on the first day that the shares are either transferable or not subject to a substantial risk of forfeiture. The ordinary income recognized will equal the excess of the fair market value of our common stock on such date over the amount, if any, the participant paid for the Restricted Stock Award. However, even if the shares under a Restricted Stock Award are both nontransferable and subject to a substantial risk of forfeiture, the participant may make a special "83(b) election" to recognize income, and have his or her tax consequences determined, as of the date the Restricted Stock Award is made. The participant's tax basis in the shares received will equal the income recognized plus the price, if any, paid for the Restricted Stock Award. Any gain (or loss) that a participant realizes upon the sale of any of our common stock acquired pursuant to a Restricted Stock Award will be equal to the amount by which the amount realized on the disposition exceeds (or is less than) the participant's tax basis in the shares and will be treated as long-term (if the shares are held for more than one year) or short-term (if the shares are held for one year or less) capital gain or loss. The participant's holding period for the stock begins on the date the shares are either transferable or not subject to a substantial risk of forfeiture, except that the holding period will begin on the date of grant if the participant makes the special "83(b) election." We or our affiliate will be entitled to a federal income tax deduction equal to the ordinary income the participant recognizes. If the participant is an employee, that ordinary income will constitute wages subject to withholding and employment taxes.

Any grant, exercise, vesting or payment of an award may be postponed if we reasonably believes that our or any applicable affiliate's deduction with respect to such award would be limited or eliminated by application of Code Section 162(m) to the extent permitted by Section 409A of the Code; provided, however, such delay will last only until the earliest date at which we reasonably anticipates the deduction will not be limited or eliminated under Code Section 162(m).

Other Tax Rules. The 2014 Plan is designed to enable the Compensation Committee to structure awards that are intended to not be subject to Code Section 409A, which imposes certain restrictions and requirements on deferred compensation

Ohr Pharmaceutical, Inc. 2009 Stock Incentive Plan

The 2009 Plan was first adopted by the board of directors in June 2009 and by the shareholders effective as of July 13, 2009. The 2009 Plan was designed to encourage ownership of common stock by employees, consultants and directors of us and our affiliates and to provide additional incentive for them to promote the success of the our business. The 2009 Plan provided for the grant of ISOs, NQSOs, restricted stock, and combinations of the above.

The 2009 Plan is administered by our Compensation Committee. An award under the 2009 Plan may grant to any employee of or consultant to one or more of us and our affiliates or to any non-employee member of the board of directors or of any board of directors (or similar governing authority) of any affiliate.

As described above, the 2016 Plan is intended to consolidate the 2014 Plan and the 2009 Plan into a new plan. For options and Restricted Stock Awards granted under the 2009 Plan prior to January 7, 2016, the terms and conditions of the 2009 Plan and the applicable award agreements will control, except that the our Compensation Committee, in its discretion may allow a participant to pay all or part of the option price (i) by surrendering shares of common stock to us that the participant already owns and, if necessary to avoid adverse accounting consequences, has held for at least six months; (ii) by a cashless exercise through a broker; (iii) by means of a "net exercise" procedure, (iv) by such other medium of payment as the Compensation Committee in its discretion shall authorize or (v) by any combination of the aforementioned methods of payment. If shares of common stock are used to pay all or part of the option price, the sum of the cash and cash equivalent and the fair market value (determined as of the day preceding the date of exercise) of the shares surrendered shall equal the option price of the shares for which the option is being exercised.

The following is only a summary of the material terms of the 2009 Plan, is not a complete description of all provisions of the 2009 Plan and should be read in conjunction with the 2009 Plan, which is filed as an exhibit to this Annual Report on Form 10-K.

Summary of the 2009 Plan

The exercise price of an ISO granted under the 2009 Plan may not be less than 100% (110% in the case of 10% stockholders) of the fair market value of the common stock at the time of grant. The exercise price of a NQSO granted under the 2009 Plan is determined by the board of directors. The term of each option may be set by the board of directors but cannot exceed ten years from grant (five years from grant in the case of an ISO granted to a 10% stockholder), and each option will be exercisable at such time or times as the board of directors specifies. The option price may be paid in cash or check acceptable to us or, if permitted by the board of directors and subject to certain additional limitations, by tendering shares of common stock, by using a promissory note, by delivering to us an unconditional and irrevocable undertaking by a broker promptly to deliver sufficient funds to pay the exercise price, or a combination of the foregoing.

The option price may be paid in cash or check acceptable to us or, if permitted by the board of directors and subject to certain additional limitations, by (i) shares of stock having a market value equal to the exercise price of the shares to be purchased, or (ii) by using a promissory note.

If a participant's employment or other association with us and our affiliates ends for any reason, any outstanding option of the participant will cease to be exercisable in any respect not later than 30 days following that event and, for the period it remains exercisable following that event, will be exercisable only to the extent exercisable at the date of that event. Military or sick leave or other bona fide leave will not be deemed a termination of employment or other association.

Unless the Compensation Committee provided otherwise for any Restricted Stock Award, upon termination of a participant's employment or other association with us and our affiliates for any reason during the restriction period, all shares of restricted stock subject to forfeiture will be forfeited or otherwise subject to return to or repurchase by us on the terms specified in the award agreement.

In the event of a Change in Control (as defined in the 2009 Plan), any Restricted Stock Award still then subject to a forfeiture and any outstanding option not then exercisable in full shall vest under the terms of the award. The Compensation Committee shall have the discretion, exercisable either in advance of a change in control or at the time thereof, to provide (upon such terms as it may deem appropriate) for (i) the automatic acceleration of one or more outstanding options that do not otherwise accelerate by reason of the change in control, and/or (ii) the subsequent termination of one or more of our repurchase rights with respect to restricted stock awards that do not otherwise terminate at that time, in the event that the employment of the respective grantees of such awards should subsequently terminate following such change in control.

Material U.S. Federal Income Tax Consequences

The following discussion summarizes the principal United States federal income tax consequences associated with awards granted under the 2009 Plan to U.S. citizens. The discussion is based on laws, regulations, rulings and court decisions currently in effect, all of which are subject to change.

ISOs. A participant will not recognize taxable income on the grant or exercise of an ISO. A participant will recognize taxable income when he or she disposes of the shares of our common stock acquired under the ISO. If the disposition occurs after the ISO holding period, the participant will recognize long-term capital gain (or loss) to the extent the amount realized from the disposition exceeds (or is less than) the participant's tax basis in the shares of our common stock. A participant's tax basis in shares of our common stock generally will be the amount the participant paid for the shares.

If our common stock acquired under an ISO is disposed of before the expiration of the ISO holding period described above, the participant will recognize as ordinary income in the year of the disposition the excess of the fair market value of our common stock on the date of exercise of the ISO over the exercise price. Any additional gain will be treated as long-term or short-term capital gain, depending on the length of time the participant held the shares. A special rule applies to such a disposition where the amount realized is less than the fair market value of our common stock on the date of exercise of the ISO. In that case, the ordinary income the participant will recognize will not exceed the excess of the amount realized on the disposition over the exercise price. If the amount realized is less than the exercise price, the participant will recognize a capital loss (long-term if the stock was held more than one year and short-term if held one year or less). A participant will receive different tax treatment if the exercise price is paid by delivery of common stock the participant already owns.

Neither us nor any of our affiliates will be entitled to a federal income tax deduction with respect to the grant or exercise of an ISO. However, in the event a participant disposes of our common stock acquired under an ISO before the expiration of the ISO holding period described above, we or our affiliate will be entitled to a federal income tax deduction equal to the amount of ordinary income the participant recognizes.

NQSOs. A participant will not recognize any taxable income on the grant of a NQSO. On the exercise of a NQSO, the participant will recognize as ordinary income the excess of the fair market value of our common stock acquired over the exercise price. A participant's tax basis in our common stock is the amount paid plus any amounts included in income on exercise. The participant's holding period for the stock begins on acquisition of the shares. Any gain or loss that a participant realizes on a subsequent disposition of our common stock acquired on the exercise of a NQSO generally will be treated as long-term or short-term capital gain or loss, depending on the length of time the participant held such shares. The amount of the gain (or loss) will equal the amount by which the amount realized on the subsequent disposition exceeds (or is less than) the participant's tax basis in his or her shares. A participant will receive different tax treatment if the exercise price is paid by delivery of Ohr common stock the participant already owns.

The exercise of a NQSO will entitle us or our affiliate to claim a federal income tax deduction equal to the amount of ordinary income the participant recognizes. If the participant is an employee, that ordinary income will constitute wages subject to withholding and employment taxes.

Restricted Stock Awards. A participant will recognize ordinary income on account of a Restricted Stock Award on the first day that the shares are either transferable or not subject to a substantial risk of forfeiture. The ordinary income recognized will equal the excess of the fair market value of our common stock on such date over the amount, if any, the participant paid for the Restricted Stock Award. However, even if the shares under a Restricted Stock Award are both nontransferable and subject to a substantial risk of forfeiture, the participant may make a special "83(b) election" to recognize income, and have his or her tax consequences determined, as of the date the Restricted Stock Award is made. The participant's tax basis in the shares received will equal the income recognized plus the price, if any, paid for the Restricted Stock Award. Any gain (or loss) that a participant realizes upon the sale of any of our common stock acquired pursuant to a Restricted Stock Award will be equal to the amount by which the amount realized on the disposition exceeds (or is less than) the participant's tax basis in the shares and will be treated as long-term (if the shares are held for more than one year) or short-term (if the shares are held for one year or less) capital gain or loss. The participant's holding period for the stock begins on the date the shares are either transferable or not subject to a substantial risk of forfeiture, except that the holding period will begin on the date of grant if the participant makes the special "83(b) election." We or our affiliate will be entitled to a federal income tax deduction equal to the ordinary income the participant recognizes. If the participant is an employee, that ordinary income will constitute wages subject to withholding and employment taxes.

Any grant, exercise, vesting or payment of an award may be postponed if we reasonably believes that our or any applicable affiliate's deduction with respect to such award would be limited or eliminated by application of Code Section 162(m) to the extent permitted by Section 409A of the Code; provided, however, such delay will last only until the earliest date at which we reasonably anticipates the deduction will not be limited or eliminated under Code Section 162(m).

Other Tax Rules. The 2009 Plan is designed to enable the Compensation Committee to structure awards that are intended to not be subject to Code Section 409A, which imposes certain restrictions and requirements on deferred compensation.

Director Compensation

Prior to the Merger, Ohr compensated its non-employee directors for their service on the Ohr board of directors. Non-employee members of the Ohr board of directors received a combination of cash compensation, in the form of annual retainers, and equity incentive compensation, in the form of stock option awards, for their service on the Ohr board of directors.

Upon the completion of the Merger, we adopted a new non-employee director compensation policy pursuant to which our non-employee directors are eligible to receive cash and equity compensation. Each non-employee director is entitled to receive an annual cash retainer of $25,000, paid quarterly. In addition, each non-employee director was granted a non-statutory stock option to purchase 227,330 shares of our common stock with an exercise price of $5.39 per share following the Merger. These options vest in equal monthly installments over a three-year period commencing on the effective date of the Merger. We expect to pay an annual retainer to our directors for committee membership in addition to the cash retainer for director service.

Non-Employee Director Compensation for 2019

Below is a summary of the non-employee director compensation paid in the fiscal year ended September 30, 2019:

Name	Cash Compensation (1)	Option Grants (2)	Stock Awards (3)	Total
June Almenoff (4)	$ 10,000	$ —	$ —	$ 10,000
Orin Hirschman (5)	$ 10,000	$ —	$ —	$ 10,000
Thomas Riedhammer (6)	$ 10,000	$ —	$ —	$ 10,000
Hon. Michael Ferguson (7)	$ 10,000	$ —	$ —	$ 10,000
Dov A. Goldstein, M.D. (8)	$ 6,250	$ 841,121	$ —	$ 847,371
Diego Miralles, M.D. (9)	$ 6,250	$ 841,121	$ —	$ 847,371
Franklyn G. Prendergast, M.D., Ph.D. (10)	$ 6,250	$ 841,121	$ —	$ 847,371
Eric I. Richman (11)	$ 6,250	$ 841,121	$ —	$ 847,371

(1) Represents the value of the annual retainers payable to our non-employee directors. Dr. Goldstein, Dr. Miralles, Dr. Prendergast, and Mr. Richman each were entitled to receive $6,250 for Board services in the year ended September 30, 2019, which were paid in October 2019.

(2) Represents the grant date fair value of the stock options granted in 2019, computed in accordance with FASB ASC Topic 718. As of September 30, 2019, each of our current non-employee directors held stock options to purchase the following number of shares of our common stock: Dr. Goldstein, options to purchase 227,330 shares; Dr. Miralles, options to purchase 227,330 shares; Dr. Prendergast, options to purchase 227,330 shares; and Mr. Richman, options to purchase 227,330 shares.

(3) No stock awards were granted to the directors in 2019.

(4) Ms. Almenoff resigned from our board of directors on July 12, 2019 in connection with the completion of the Merger.

(5) Mr. Hirschman resigned from our board of directors on July 12, 2019 in connection with the completion of the Merger.

(6) Mr. Riedhammer resigned from our board of directors on July 12, 2019 in connection with the completion of the Merger.

(7) The Hon. Michael Ferguson resigned from our board of directors on July 12, 2019 in connection with the completion of the Merger.

(8) Dr. Goldstein was appointed our board of directors on July 12, 2019 in connection with the completion of the Merger.

(9) Dr. Miralles was appointed our board of directors on July 12, 2019 in connection with the completion of the Merger.

(10) Dr. Prendergast was appointed our board of directors on July 12, 2019 in connection with the completion of the Merger.

(11) Mr. Richman was appointed our board of directors on July 12, 2019 in connection with the completion of the Merger.

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

Equity Compensation Plan Information

See Item 5 of Part II of this Annual Report on Form 10-K regarding information about securities authorized for issuance under our equity compensation plans.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information with respect to the beneficial ownership, as of September 30, 2019, of our common stock by (a) each of our Named Executive Officers and current directors individually, (b) our current directors and executive officers as a group and (c) each holder of more than 5% of our outstanding common stock. This table is based upon information supplied by officers, directors and principal stockholders and a review of Schedules 13D and 13G, if any, filed with the SEC. Other than as set forth below, we are not aware of any other beneficial owner of more than five percent of our common stock as of September 30, 2019. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons and entities named in the table below have sole voting and investment power with respect to all shares of common stock that they beneficially own, subject to applicable community property laws.

Beneficial ownership and percentage ownership are determined in accordance with the Rule 13d-3 of the Exchange Act. Under these rules, shares of our common stock issuable under stock options that are exercisable within 60 days of the Reference Date are deemed outstanding for the purpose of computing the percentage ownership of the person holding the options, but are not deemed outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated and subject to applicable community property laws, to our knowledge, each stockholder named in the following table possesses sole voting and investment power over their shares of our common stock, except for those jointly owned with that person’s spouse.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Class (%) (1)
Dietrich Stephan, Ph.D. (2)	5,859,569	28.7%
Entities affiliated with Greenlight Capital, Inc. (3)	1,538,462	9.0%
Carnegie Mellon University (4)	939,412	5.5%
Shivaji Thadke (5)	1,019,055	6.0%
Shawn Milemore Titcomb and Jennifer Bove Titcomb Joint Living Trust (6)	861,394	5.0%
Directors and Named Executive Officers (7)		
Sam Backenroth, Chief Financial Officer (8)	30,631	*
Jason S. Slakter, M.D., Former Chief Executive Officer (9)	137,683	*
Dov A. Goldstein, M.D., Director (10)	25,258	*
Diego Miralles, M.D., Director (11)	25,258	*
Franklyn G. Prendergast, M.D., Ph.D., Director (12)	25,258	*
Eric I. Richman, Director (13)	50,505	*
All current executive officers and directors as a group (six persons) (14)	6,016,479	29.3%

* Less than one percent.

(1) Percentage ownership is calculated based on a total of 17,077,873 shares of our common stock issued and outstanding as of September 30, 2019.

(2) Represents (i) 3,311,930 shares of common stock issuable pursuant to stock options exercisable within 60 days after September 30, 2019 and (ii) 2,547,639 shares of our common stock held directly by Lipizzaner LLC, of which Dr. Stephan is the sole member.

(3) Represents (i) 957,331 shares of our common stock held directly by Greenlight Capital, Inc. and (ii) 581,131 shares of our common stock held by DME Capital Management, LP. Greenlight Capital, Inc. holds the shares of our common stock for certain private investment funds and other accounts for which Greenlight Capital, Inc. acts as the investment manager (or general partner of the investment manager). The address of Greenlight Capital, Inc. is 140 East 45th Street, 24th Floor, New York, NY 10017.

(4) Represents 939,412 shares of our common stock held by Carnegie Mellon University. The address for Carnegie Mellon University is 5000 Forbes Avenue, Pittsburgh, PA 15213.

(5) Represents 1,019,055 shares of our common stock held by Shivaji Thadke. The address for Shivaji Thadke is 700 Technology Drive, Third Floor, Pittsburgh, PA 15219.

(6) Represents 861,394 shares of our common stock held by the Shawn Milemore Titcomb and Jennifer Bove Titcomb Joint Living Trust. The address for Shawn Milemore Titcomb and Jennifer Bove Titcomb Joint Living Trust is 900 N. Federal Hwy., Suite 400, Boca Raton, Florida 33432.

(7) Unless otherwise indicated, the address for each of our executive officers and directors is c/o 700 Technology Drive, Third Floor, Pittsburgh, PA 15219.

(8) Represents (i) 2,501 shares of common stock issuable pursuant to warrants exercisable within 60 days after September 30, 2019, (ii) 17,500 shares of common stock issuable pursuant to option exercisable within 60 days after September 30, 2019, and (iii) 10,630 shares of our common stock held directly by Sam Backenroth.

(9) Represents (i) 5,001 shares of common stock issuable pursuant to warrants exercisable within 60 days after September 30, 2019, (ii) 19,500 shares of common stock issuable pursuant to stock options exercisable within 60 days after September 30, 2019, and (iii) 113,182 shares of our common stock held directly by Jason S. Slakter, M.D. Dr. Slakter was appointed President and Chief Executive Officer of Ohr in September 2015. Dr. Slakter resigned from Ohr on July 12, 2019 in connection with the completion of the Merger.

(10) Represents 25,258 shares of common stock issuable pursuant to stock options exercisable within 60 days after September 30, 2019 held directly by Dov A. Goldstein, M.D.

(11) Represents 25,258 shares of common stock issuable pursuant to stock options exercisable within 60 days after September 30, 2019 held directly by Diego Miralles, M.D.

(12) Represents 25,258 shares of common stock issuable pursuant to stock options exercisable within 60 days after September 30, 2019 held directly by Franklyn G. Prendergast, M.D., Ph.D.

(13) Represents (i) 25,258 shares of common stock issuable pursuant to stock options exercisable within 60 days after September 30, 2019 and (ii) 25,247 shares of our common stock held by Eric I. Richman jointly with his spouse.

(14) Comprised of shares beneficially owned by each of our directors, including Dr. Stephan, our President and Chief Executive Officer, and Sam Backenroth, our Chief Financial Officer, Treasurer and Secretary.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Described below are any transactions occurring since October 1, 2018 and any currently proposed transactions to which we were a party and in which:

- the amounts involved exceeded or will exceed $120,000; and
- a director, executive officer, holder of more than 5% of the outstanding capital stock of NeuBase, or any member of such person's immediate family had or will have a direct or indirect material interest.

Our board of directors has adopted a written related policy with respect to related person transactions. This policy governs the review, approval or ratification of covered related person transactions. The Audit Committee of our board of directors (the "Audit Committee") manages this policy.

For purposes of this policy, a "related person transaction" is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we (or any of our subsidiaries) were, are or will be a participant, and the amount involved exceeds $120,000 and in which any related person had, has or will have a direct or indirect interest. For purposes of determining whether a transaction is a related person transaction, the Audit Committee relies upon Item 404 of Regulation S-K, promulgated under the Exchange Act.

A "related person" is defined as:

- Any person who is, or at any time since the beginning of our last fiscal year was, one of our directors or executive officers or a nominee to become one of our directors;
- any person who is known to be the beneficial owner of more than five percent of any class of our voting securities;
- any immediate family member of any of the foregoing persons, which means any child, stepchild, parent, stepparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law or sister-in-law of the director, executive officer, nominee or more than five percent beneficial owner, and any person (other than a tenant or employee) sharing the household of such director, executive officer, nominee or more than five percent beneficial owner; or
- any firm, corporation, or other entity in which any of the foregoing persons is employed or is a general partner or principal or in a similar position or in which such person has a ten percent or greater beneficial ownership interest.

The policy generally provides that we may enter into a related person transaction only if:

- the Audit Committee pre-approves such transaction in accordance with the guidelines set forth in the policy;
- the transaction is on terms comparable to those that could be obtained in arm's length dealings with an unrelated third party and the Audit Committee (or the chairperson of the Audit Committee) approves or ratifies such transaction in accordance with the guideline set forth in the policy;
- the transaction is approved by the disinterested members of our board of directors; or
- the transaction involves compensation approved by our Compensation Committee.

In the event a related person transaction is not pre-approved by the Audit Committee and our management determines to recommend such related person transaction to the Audit Committee, such transaction must be reviewed by the Audit Committee. After review, the Audit Committee will approve or disapprove such transaction. When our Chief Financial Officer in consultation with our Chief Executive Officer, determines that it is not practicable or desirable for us to wait until the next Audit Committee meeting, the chairperson of the Audit Committee possesses delegated authority to act on behalf of the Audit Committee. The Audit Committee (or the chairperson of the Audit Committee) may approve only those related person transactions that are in, or not inconsistent with, our best interests and the best interests of our stockholders, as the Audit Committee (or the chairperson of the Audit Committee) determines in good faith.

Our Audit Committee has determined that certain types of related person transactions are deemed to be pre-approved by our Audit Committee. Our related person transaction policy provides that the following transactions, even if the amount exceeds $120,000 in the aggregate, are considered to be pre-approved by the our Audit Committee:

- any employment of certain named executive officers that would be publicly disclosed;
- director compensation that would be publicly disclosed;
- transactions with other companies where the related person's only relationship is as a director or owner of less than ten percent of said company (other than a general partnership), if the aggregate amount involved does not exceed the greater of $200,000 or five percent of that company's consolidated gross revenues;
- transactions where all stockholders receive proportional benefits;
- transactions involving competitive bids;
- transactions with a related person involving the rendering of services at rates or charges fixed inconformity with law or governmental authority; and
- transactions with a related person involving services as a bank depositary of funds, transfer agent, registrar, trustee under a trust indenture or similar services.

In addition, our Audit Committee will review the policy at least annually and recommend amendments to the policy to our board of directors from time to time.

The policy provides that all related person transactions will be disclosed to our Audit Committee, and all material related person transactions will be disclosed to our board of directors. Additionally, all related person transactions requiring public disclosure will be disclosed, as applicable, on our various public filings.

Our Audit Committee will review all relevant information available to it about the related person transaction. The policy provides that the Audit Committee may approve or ratify the related person transaction only if our Audit Committee determines that, under all of the circumstances, the transaction is in, or is not inconsistent with, our best interests. The policy provides that our Audit Committee may, in its sole discretion, impose such conditions as it deems appropriate on us or the related person in connection with approval of the related person transaction.

Transactions with Related Persons

DARC Contract

During the Mako trial, Ohr's CRO running its Phase III trial had contracted with Jason S. Slakter, M.D., P.C., d/b/a Digital Angiography Reading Center ("DARC"), a well-known digital reading center, which is owned by Dr. Slakter, Ohr's former CEO, pursuant to Ohr's related party transactions policy, with the review and approval of the Audit Committee, to provide digital reading and imaging services in connection with the Phase III MAKO study. Ohr indirectly paid DARC $899,001 in the fiscal year 2018, for services rendered to Ohr. No payments were made to DARC in the fiscal year 2019.

Dr. Slakter Retention Bonus Agreement

In connection with the Merger, on January 2, 2019, Ohr entered into the Retention Bonus Agreement with Dr. Jason Slakter, our former CEO. Under the Retention Bonus Agreement, Dr. Slakter was eligible for a retention bonus payment of $75,000 upon the earliest to occur of the following: (i) Dr. Slakter's continued service with us as CEO through and including the closing date of the Merger, or (ii) Dr. Slakter is involuntarily separated from service without Cause (as such term is defined in the Retention Bonus Agreement) by us prior to the closing date of the Merger. In the event Dr. Slakter voluntarily separated from service with us for any reason prior to the closing of the Merger, Dr. Slakter would not receive any retention bonus payment and we would have no further obligation to Dr. Slakter under the Retention Bonus Agreement.

Pursuant to the Retention Bonus Agreement, upon the closing the Merger, Dr. Slakter was entitled to receive a retention bonus payment of $75,000 for his continued service to us since January 2, 2019. The bonus was paid in July 2019.

Ohr Support Agreements

In order to induce Legacy NeuBase to enter into the Merger Agreement, certain Ohr securityholders that beneficially own or control 8.9% as of June 3, 2019, including Dr. Slakter, our former CEO, and Mr. Sam Backenroth, our CFO, entered into support agreements pursuant to which, among other things, they agreed to vote all their shares of Ohr capital stock: in favor of the adoption of the Merger Agreement and the approval of the transactions contemplated thereby, including the Merger and the issuance of Ohr common stock and a reverse stock split of our common stock in connection with, or related to, the consummation of the Merger; against any action or agreement that, to the knowledge of such securityholders, would reasonably be expected to result in a breach in any material respect of any covenant, representation or warranty or any other obligation or agreement of Ohr or any of its subsidiaries or affiliates under the Merger Agreement or that would reasonably be expected to result in any of the conditions to Ohr's or any of its subsidiaries' or affiliates' obligations under the Merger Agreement not being fulfilled; and against any "acquisition proposal", or any agreement, transaction or other matter that is intended to, or would reasonably be expected to, impede, interfere with, delay, postpone, discourage or materially and adversely affect the consummation of the Merger and all other transactions contemplated by the Merger Agreement. Such securityholders also agreed not to take any actions inconsistent with the foregoing obligations, except in the event that the Ohr board of directors withdraws or modifies its recommendation of the Merger.

The following transactions were entered into by Legacy NeuBase prior to the completion of the Merger.

Dr. Stephan Indemnification Agreement

In August 2018, Legacy NeuBase entered into an indemnification agreement with Dr. Stephan, which provides for the advancement of expenses under certain conditions and required Legacy NeuBase to indemnify Dr. Stephan in connection with his role as an executive officer and director of Legacy NeuBase to the fullest extent permitted by the DGCL.

Dr. Stephan Restricted Stock Purchase Agreement; Option Grant

On September 6, 2018, Dr. Stephan entered into a Restricted Stock Purchase Agreement with Legacy NeuBase, pursuant to which Dr. Stephan purchased 2,500,000 shares of Legacy NeuBase's common stock at a purchase price of $0.00001 per share for a total purchase price of $25.00, which were converted into 2,547,639 shares of our common stock in the Merger. As of the date of issuance of the shares to Dr. Stephan, 25% were fully vested and the remaining 75% are scheduled to vest on an equal monthly basis over 36 months. The shares vested in full upon the closing of the Merger.

Dr. Stephan was also granted an employee stock option to acquire 3,250,000 shares of Legacy NeuBase common stock, where the shares underlying the option would vest in equal monthly installments over 48 months starting on August 28, 2018 and where 100% of the unvested shares underlying the option would immediately vest and become exercisable upon the consummation of a Change of Control (as defined in the 2018 Plan). Upon the completion of the Merger, the shares underlying the option accelerated and were exchanged for an employee stock option to acquire 3,311,930 shares of our common stock at an exercise price of $0.001 per share.

Agreement with LifeX Labs LLC

From inception through the period ended September 30, 2018, Legacy NeuBase utilized the services of LifeX Labs LLC. These services included accounting consultation and office space rental. This agreement was terminated on January 8, 2019. Dr. Stephan, our CEO, was on the board and acting as CEO of LifeX Labs LLC until December 28, 2018, when he resigned from all positions within LifeX Labs LLC. During the period ended September 30, 2019 and the period ended September 30, 2018, LifeX Labs LLC was paid $10,628 and $1,575, respectively, by Legacy NeuBase.

Dr. Stephan Support Agreement

In order to induce Ohr to enter into the Merger Agreement, certain Legacy NeuBase securityholders, including Dr. Stephan, entered into support agreements pursuant to which, among other things, they agreed to vote all of their shares of Legacy NeuBase capital stock: in favor of the adoption of the Merger Agreement and, if required, the entry of Legacy NeuBase into financing agreements for gross proceeds of $0.9 million; against any action or agreement that, to the knowledge of such securityholder, would reasonably be expected to result in a breach in any material respect of any covenant, representation or warranty or any other obligation or agreement of Legacy NeuBase or any of its subsidiaries or affiliates under the Merger Agreement or that would reasonably be expected to result in any of the conditions to Legacy NeuBase's or any of its subsidiaries' or affiliates' obligations under the Merger Agreement not being fulfilled; and against any "acquisition proposal", or any agreement, transaction or other matter that is intended to, or would reasonably be expected to, impede, interfere with, delay, postpone, discourage or materially and adversely affect the consummation of the merger and all other transactions contemplated by the Merger Agreement. Such securityholders also agreed not to take any actions inconsistent with the foregoing obligations.

Indemnification Agreements With Directors and Executive Officers

We have entered into indemnification agreements with our directors and executive officers under which we agreed to indemnify those individuals, under the circumstances and to the extent provided for in the agreements, for expenses, damages, judgments, fines, penalties, settlements and any other amounts they may be required to pay in actions, suits or proceedings which they are or may be made a party or threatened to be made a party by reason of their position as a director, officer or other agent of ours, and otherwise to the fullest extent permitted under Delaware law and our amended and restated certificate of incorporation and Restated Bylaws. We believe that these indemnification agreements are necessary to attract and retain qualified directors, officers and other key employees.

Director Independence

Our common stock is listed on the Nasdaq Global Market. Under the rules of Nasdaq Stock Market LLC (the "Nasdaq Rules"), independent directors must comprise a majority of a listed company's board of directors. In addition, the Nasdaq Rules require that, subject to specified exceptions, each member of a listed company's audit, compensation, and nominating and corporate governance committees be independent. Under the Nasdaq Rules, a director will only qualify as an "independent director" if, in the opinion of the listed company's board of directors, the director does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Audit Committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act and the Nasdaq Rules. In addition, Compensation Committee members must satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act and the Nasdaq Rules.
Our board of directors has determined that each of Drs. Goldstein, Miralles, Prendergast and Mr. Richman met the definitions of independence under the Nasdaq Marketplace Rules and Section 10A-3 of Exchange Act. Accordingly, all of our directors, other than our Chief Executive Officer, Dr. Stephan, are deemed to be independent.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Changes in Independent Registered Public Accounting Firm

On October 2, 2019, our Audit Committee dismissed MaloneBailey, LLP ("MaloneBailey") as our independent registered public accounting firm effective as of that date.

MaloneBailey's audit report on our consolidated financial statements for the fiscal year ended September 30, 2018 did not contain any adverse opinion or disclaimer of opinion and was not qualified or modified as to uncertainty, audit scope, or accounting principles, except with respect to an explanatory paragraph indicating that there was substantial doubt about our ability to continue as a going concern.

During the fiscal years ended September 30, 2019 and September 30, 2018, and the subsequent interim period from October 1, 2019 through October 2, 2019, there were (i) no disagreements within the meaning of Item 304(a)(1)(iv) of Regulation S-K between us and MaloneBailey on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to MaloneBailey's satisfaction, would have caused MaloneBailey to make reference to the subject matter of the disagreements in connection with its reports on our consolidated financial statements for such years, and (ii) no "reportable events" within the meaning of Item 304(a)(1)(v) of Regulation S-K.

On October 2, 2019, the Audit Committee approved, effective immediately, the engagement of CohnReznick LLP ("CohnReznick") as our independent registered public accounting firm for the fiscal year ended September 30, 2019.

During the fiscal years ended September 30, 2019 and September 30, 2018, and the subsequent interim period from October 1, 2019 through October 2, 2019, neither us nor anyone acting on behalf of us, has consulted with CohnReznick regarding (i) the application of accounting principles to a specific transaction, either completed or proposed, or the type of audit opinion that might be rendered on our consolidated financial statements, and neither a written report nor oral advice was provided to us that CohnReznick concluded was an important factor considered by us in reaching a decision as to any accounting, auditing or financial reporting issue, (ii) any matter that was subject of a disagreement within the meaning of Item 304(a)(1)(iv) of Regulation S-K, or (iii) any "reportable event" within the meaning of Item 304(a)(1)(v) of Regulation S-K.

Fees for Independent Registered Public Accounting Firm

The following is a summary of the fees billed to us by MaloneBailey, LLP, our former independent registered public accounting firm, and CohnReznick, our current independent registered public accounting firm, for professional services rendered for the fiscal years ended September 30, 2019 and 2018, respectively:

	2019	2018
Audit Fees (1):	$ 351,909	$ 89,000
Audit-Related Fees (2):	—	—
Tax Fees (3):	—	—
All Other Fees (4):	—	—
Total All Fees:	$ 351,909	$ 89,000

(1) Audit Fees consist of $250,000 of actual and estimated fees for professional services performed by CohnReznick for the audit of our 2019 annual financial statements that are included in our Form 10-K filing. Audit fees also include $101,109 of 2019 fees and $89,000 of 2018 fees for professional services performed by MaloneBailey for the audit of our annual financial statements included in our prior Form 10-K filing, review of financial statements included in our quarterly Form 10-Q filings, and reviews of registration statements and issuances of consents, comfort letters and services that are normally provided in connection with statutory and regulatory filings or engagements.

(2) Audit-Related Fees consist of fees for other audit-related professional services.

(3) Consists of fees for tax compliance and consulting.

(4) No other fees were earned or paid for fiscal 2018 or fiscal 2019.

Pre-Approval Policies and Procedures

All audit and non-audit services previously provided by our independent registered public accounting firm must be pre-approved by the Audit Committee. Pre-approval may be given for a category of services, provided that (i) the category is reasonably narrow and detailed and (ii) the Audit Committee establishes a fee limit for such category. The Audit Committee may delegate to any other member of the Audit Committee the authority to grant pre-approval of permitted non-audit services to be provided by CohnReznick between Audit Committee meetings; provided, however, that any such pre-approval shall be presented to the full Audit Committee at its next scheduled meeting. The Audit Committee pre-approved all audit and permitted non-audit services provided by MaloneBailey and CohnReznick for professional services rendered for the fiscal years ended September 30, 2019 and 2018.

PART IV.

ITEM 15. EXHIBITS

(a) 1. Financial Statements
The information required by this item is included in Item 8 of Part II of this Form 10-K.

2. Financial Statement Schedules
The information required by this item is included in Item 8 of Part II of this Form 10-K.

3. Exhibits
The following exhibits are incorporated by reference or filed as part of this report:

Exhibit Number	Description	Incorporated by Reference			
		Form	File Number	Filing Date	Exhibit
2.1+	Agreement and Plan of Merger and Reorganization, dated as of January 2, 2019, by and among Ohr Pharmaceutical, Inc., Ohr Acquisition Corp. and NeuBase Therapeutics, Inc.	8-K	001-35963	1/3/2019	2.1
2.2	Form of Support Agreement, by and among Ohr Pharmaceutical, Inc., NeuBase Therapeutics Inc. and the directors and officers of Ohr Pharmaceutical, Inc.	8-K	001-35963	1/3/2019	2.2
2.3	Form of Support Agreement by and among NeuBase Therapeutics, Inc., Ohr Pharmaceutical, Inc. and its directors, officers, and certain stockholders of NeuBase Therapeutics, Inc.	8-K	001-35963	1/3/2019	2.3
2.4	Form of Ohr Pharmaceutical, Inc. and NeuBase Therapeutics, Inc. Lock-Up Agreements.	8-K	001-35963	1/3/2019	2.4
2.5	First Amendment to the Agreement and Plan of Merger and Reorganization, dated as of June 27, 2019, by and among Ohr Pharmaceutical, Inc., Ohr Acquisition Corp. and NeuBase Therapeutics, Inc.	8-K	001-35963	7/3/2019	2.1
3.1	Amended and Restated Certificate of Incorporation of the Company.	8-K	001-35963	7/12/2019	3.1
3.2	Amended and Restated Bylaws of the Company.	8-K	001-35963	9/23/2019	3.1
4.1	Form of Consulting Warrants.	10-Q	001-35963	8/15/2011	10.21
4.2	Form of Series A Warrant issued to investors pursuant to the Securities Purchase Agreement, dated December 7, 2016, by and among Ohr Pharmaceutical, Inc. and the purchasers listed therein.	8-K	001-35963	12/8/2016	4.1
4.3	Form of Warrant issued to investors pursuant to the Securities Purchase Agreement, dated as of April 5, 2017, by and among Ohr Pharmaceutical, Inc. and the purchasers listed therein.	8-K	001-35963	4/6/2017	4.1
4.4	Form of Common Stock Certificate.	S-8	333-233346	8/16/2019	4.17
4.5*	Description of Securities of NeuBase Therapeutics, Inc.				
10.1#	Employment Agreement, dated January 8, 2014, between Ohr Pharmaceutical, Inc. and Sam Backenroth.	8-K	001-35963	1/10/2014	10.38
10.2#	Amendment 1 to Employment Agreement, dated as of January 6, 2015, between Ohr Pharmaceutical, Inc. and Sam Backenroth.	8-K	001-35963	1/8/2015	10.51
10.3	Proprietary Information and Inventions Agreement, dated April 10, 2010, between Ohr Pharmaceutical, Inc. and Sam Backenroth.	10-K	001-35963	12/14/2015	10.3(c)
10.4	Securities Purchase Agreement, dated December 7, 2016, by and among Ohr Pharmaceutical, Inc. and to purchasers listed therein.	8-K	001-35963	12/8/2016	10.1
10.5	Securities Purchase Agreement, dated April 5, 2017, by and among Ohr Pharmaceutical, Inc. and to purchasers listed therein.	8-K	001-35963	4/6/2017	10.1
10.6#	Ohr Pharmaceutical, Inc. 2016 Consolidated Stock Incentive Plan.	8-K	001-35963	3/21/2016	10.1

10.7#	Form of Stock Option Agreement (2016 Consolidated Stock Incentive Plan).	10-K	001-35963	12/15/2017	10.11(b)
10.8#	Form of Restricted Stock Agreement (2016 Consolidated Stock Incentive Plan).	10-K	001-35963	12/15/2017	10.11(c)
10.9#	Ohr Pharmaceutical, Inc. 2014 Stock Incentive Plan.	8-K	001-35963	4/14/2014	10.42
10.10#	Amendment to Ohr Pharmaceutical, Inc. 2014 Stock Incentive Plan.	10-K	001-35963	12/14/2015	10.8(b)
10.11#	Form of Stock Option Agreement (2014 Stock Incentive Plan).	10-Q	001-35963	5/11/2015	10.53
10.12#	Ohr Pharmaceutical, Inc. 2009 Stock Incentive Plan.	10-Q	001-35963	5/17/2010	10.1
10.13#	Retention Bonus Agreement, dated as of January 2, 2019, by and between Ohr Pharmaceutical, Inc. and Jason Slakter.	8-K	001-35963	1/3/2019	10.1
10.14†	License Agreement, dated December 17, 2018, by and between NeuBase Therapeutics, Inc. and Carnegie Mellon University.	S-4	333-230168	3/8/2019	10.15
10.15	Form of NeuBase Therapeutics, Inc. Warrant Certificate.	S-4	333-230168	3/8/2019	10.16
10.16#	NeuBase Therapeutics, Inc. 2018 Equity Incentive Plan.	S-4	333-230168	3/8/2019	10.19
10.17	Restricted Stock Purchase Agreement, made as of September 6, 2018, by and between NeuBase Therapeutics, Inc. and Dietrich A. Stephan.	S-4	333-230168	3/8/2019	10.21
10.18	Amendment to Restricted Stock Purchase Agreement, made as of December 26, 2018, by and between NeuBase Therapeutics, Inc. and Dietrich A. Stephan.	S-4	333-230168	3/8/2019	10.22
10.19#	Executive Employment Agreement, entered into as of December 22, 2018 and effective as of August 28, 2018, by and between NeuBase Therapeutics, Inc. and Dietrich A. Stephan.	S-4/A	333-230168	5/7/2019	10.23
10.20#	At-Will Employment, Confidential Information, Invention Assignment and Arbitration Agreement, dated December 22, 2018, by and between NeuBase Therapeutics, Inc. and Dietrich A. Stephan.	S-4/A	333-230168	5/7/2019	10.24
10.21#	Offer Letter of Employment, dated May 22, 2019, by and between NeuBase Therapeutics, Inc. and Sam Backenroth.	S-4/A	333-230168	5/22/2019	10.25
10.22	Employee Proprietary Information and Invention Assignment Agreement, dated May 22, 2019, by and between NeuBase Therapeutics, Inc. and Sam Backenroth.	S-4/A	333-230168	5/222019	10.26
10.23	Common Stock Purchase Agreement, dated as of July 12, 2019, between the Company and the purchasers named in the signature pages thereto.	8-K	001-35963	7/12/2019	10.1
10.24	Registration Rights Agreement, dated as of July 12, 2019, between the Company and the purchasers named in the signature pages thereto.	8-K	001-35963	7/12/2019	10.2
10.25#	Offer of Employment, dated July 11, 2019, by and between NeuBase Therapeutics, Inc. and Dietrich A. Stephan.	8-K/A	001-35963	7/17/2019	10.1
10.26#	Ohr Pharmaceutical, Inc. 2019 Stock Incentive Plan.	S-4	333-230168	3/8/2019	Annex E
10.27#	Form of Option Agreement under the Ohr Pharmaceutical, Inc. 2019 Stock Incentive Plan.	S-8	333-233346	8/16/2019	4.5
10.28#	Form of Option Agreement under the NeuBase Therapeutics, Inc. 2018 Equity Incentive Plan.	S-8	333-233346	8/16/2019	4.8
10.29*	Sublease Agreement, dated as of March 12, 2019, by and between NeuBase Therapeutics, Inc. and StartUptown dba Avenu.				
10.30*	Amendment No. 1 to Sublease Agreement, dated as of May 21, 2019, by and between NeuBase Therapeutics, Inc. and StartUptown dba Avenu.				

10.31*	Amendment No. 2 to Sublease Agreement, dated as of July 29, 2019, by and between NeuBase Therapeutics, Inc. and StartUptown dba Avenu.				
16.1	Letter from MaloneBailey, LLP, dated October 3, 2019.	8-K	001-35963	10/3/2019	16.1
21.1*	Subsidiaries.				
23.1*	Consent of CohnReznick LLP.				
23.2*	Consent of MaloneBailey, LLP.				
31.1*	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes Oxley Act of 2002				
101.INS*	XBRL Instance Document.				
101.SCH*	XBRL Taxonomy Extension Schema 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.				

* Field herewith.
\+ All schedules and exhibits to the agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.
\# Management compensatory plan or arrangement.
† The SEC has granted confidential treatment with respect to certain portions of this exhibit. Those portions have been omitted and filed separately with the SEC.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

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

NeuBase Therapeutics, Inc.

Date: January 10, 2020

/s/ Dietrich Stephan, Ph.D.
Dietrich Stephan, Ph.D.
President and Chief Executive Officer

Signature	Title	Date
/s/ Dietrich Stephan, Ph.D. Dietrich Stephan, Ph.D.	President, Chief Executive Officer and Director *(Principal Executive Officer)*	January 10, 2020
/s/ Sam Backenroth Sam Backenroth	Chief Financial Officer *(Principal Financial and Accounting Officer)*	January 10, 2020
/s/ Dov A. Goldstein, M.D. Dov A. Goldstein, M.D.	Director	January 10, 2020
/s/ Diego Miralles, M.D. Diego Miralles, M.D.	Director	January 10, 2020
/s/ Franklyn G. Prendergast, M.D., Ph.D. Franklyn G. Prendergast, M.D., Ph.D.	Director	January 10, 2020
/s/ Eric I. Richman Eric I. Richman	Director	January 10, 2020

Exhibit 4.5

Description of Securities of NeuBase Therapeutics, Inc.

The authorized capital stock of NeuBase Therapeutics, Inc. (the "Company") consists of:

- 250,000,000 shares of common stock, $0.0001 par value ("Common Stock"); and
- 10,000,000 shares of preferred stock, $0.0001 par value ("Preferred Stock").

Common Stock

Except as otherwise expressly provided in the Company's Amended and Restated Certificate of Incorporation, as amended (the "Certificate of Incorporation"), or as required by applicable law, all shares of the Company's Common Stock have the same rights and privileges and rank equally, share ratably and are identical in all respects as to all matters, including, without limitation, those described below:

- ***Voting rights.*** Each holder of Common Stock is entitled to one vote per share for the election of directors and on all other matters that require stockholder approval. Holders of Common Stock do not have any cumulative voting rights. As further described below in the section titled "Anti-Takeover Effects of Provisions of the Company's Certificate of Incorporation and Delaware Law – Classified Board; Election and Removal of Directors; Filling Vacancies", the Certificate of Incorporation and the Company's Amended and Restated Bylaws, as amended (the "Bylaws"), provide for a classified board of directors consisting of three classes of approximately equal size, each serving staggered three-year terms. There is no provision for cumulative voting for the election of directors, which means that a plurality of the shares voted can elect all of the directors then standing for election. Except as provided under the General Corporation Law of the State of Delaware ("DGCL") or the Certificate of Incorporation and the Bylaws, action on a matter is approved if the votes cast favoring the action exceed the votes cast opposing the action.
- ***Dividend rights.*** The holders of outstanding shares of Common Stock are entitled to receive dividends out of funds legally available if the Company's board of directors, in its discretion, determines to issue dividends and only at the times and in the amounts that the Company's board of directors may determine and will depend upon the Company's earnings, if any, capital requirements, operating and financial conditions and on such other factors as the Company's board of directors deems relevant.
- ***Liquidation rights.*** Upon the Company's liquidation, dissolution or winding-up, the holders of Common Stock will be entitled to share equally, identically and ratably in all assets remaining, subject to the prior satisfaction of all outstanding debt and liabilities and the preferential rights and payment of liquidation preferences, if any, on any outstanding shares of Preferred Stock.
- ***No preemptive or similar rights.*** The Common Stock does not carry any redemption rights or any preemptive or preferential rights enabling a holder to subscribe for, or receive shares of, any class of Common Stock or any other securities convertible into shares of any class of Common Stock. The Common Stock is not subject to conversion, redemption or sinking fund provisions.
- ***Anti-Takeover Provisions.*** The section below titled "Anti-Takeover Effects of Provisions of the Company's Certificate of Incorporation and Delaware Law" is incorporated herein by reference.

Listing

The Company's Common Stock is listed on the Nasdaq Capital Market under the symbol "NBSE".

Preferred Stock

Under the Certificate of Incorporation, the Company's board of directors has the authority, without further action by stockholders, to designate one or more series of Preferred Stock and to fix the voting powers, designations, preferences, limitations, restrictions and relative rights granted to or imposed upon the Preferred Stock, including dividend rights, conversion rights, voting rights, rights and terms of redemption, liquidation preference and sinking fund terms, any or all of which may be preferential to or greater than the rights of the Company's Common Stock.

The Company's board of directors may authorize the issuance of Preferred Stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of Common Stock. The issuance of Preferred Stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control and may adversely affect the market price of the Common Stock and the voting and other rights of the holders of Common Stock.

The Company's board of directors may specify the following characteristics of any Preferred Stock:

- the designation and stated value, if any, of the class or series of Preferred Stock;
- the number of shares of the class or series of Preferred Stock offered, and the liquidation preference, if any, per share;
- the dividend rate(s), period(s) or payment date(s) or method(s) of calculation, if any, applicable to the class or series of Preferred Stock;
- whether dividends, if any, are cumulative or non-cumulative and, if cumulative, the date from which dividends on the class or series of Preferred Stock will accumulate;
- the provisions for a sinking fund, if any, for the class or series of Preferred Stock;
- the provision for redemption, if applicable, of the class or series of Preferred Stock;
- the terms and conditions, if applicable, upon which the class or series of Preferred Stock will be convertible into Common Stock, including the conversion price or manner of calculation and conversion period;
- voting rights, if any, of the class or series of Preferred Stock;
- the relative ranking and preferences of the class or series of Preferred Stock as to dividend rights and rights, if any, upon the liquidation, dissolution or winding up of our affairs;
- any limitations on issuance of any class or series of Preferred Stock ranking senior to or on a parity with the class or series of Preferred Stock as to dividend rights and rights, if any, upon liquidation, dissolution or winding up of our affairs; and
- any other specific terms, preferences, rights, limitations or restrictions of the class or series of Preferred Stock.

Warrants

December 2016 Warrants

On December 7, 2016, the Company entered into a securities purchase agreement with the purchasers set forth on the signature pages thereto, pursuant to which the Company agreed to issue and sell Series A Warrants to purchase shares of Common Stock (the "December 2016 Warrants"). On December 13, 2016, the Company issued the December 2016 Warrants.

As of September 30, 2019, December 2016 Warrants to purchase 20,627 shares of Common Stock were outstanding and exercisable.

Exercisability. The December 2016 Warrants were immediately exercisable upon issuance and will expire on December 13, 2021.

The December 2016 Warrants are exercisable, at the option of each holder, in whole or in part by delivering to the Company a duly executed exercise notice and by payment in full in immediately available funds for the number of shares of Common Stock purchased upon such exercise. If a registration statement registering the issuance of the shares of Common Stock underlying December 2016 Warrants under the Securities Act of 1933, as amended (the "Securities Act"), is not then effective or available, the holder may exercise the December 2016 Warrant through a cashless exercise, in whole or in part, in which case the holder would receive upon such exercise the net number of shares of Common Stock determined according to the formula set forth in the December 2016 Warrant. No fractional shares of Common Stock will be issued in connection with the exercise of a December 2016 Warrant. In lieu of fractional shares, the Company will either pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price or round up to the next whole share.

Exercise Limitation. A holder will not have the right to exercise any portion of a December 2016 Warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or on election of the holder, 9.99%) of the number of shares of the Company's Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the December 2016 Warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice to us.

Exercise Price. The exercise price per share of Common Stock purchasable upon exercise of one December 2016 Warrant is $55.00 per share of Common Stock. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the Company's Common Stock.

Transferability. Subject to applicable laws, the December 2016 Warrants may be offered for sale, sold, transferred or assigned without the Company's consent. There is currently no trading market for the December 2016 Warrants and a trading market is not expected to develop.

Exchange Listing. The December 2016 Warrants are not listed on the Nasdaq Capital Market, any other national securities exchange or any other nationally recognized trading system.

Fundamental Transactions. In the event of a fundamental transaction, the holders of the December 2016 Warrants will be entitled to receive upon exercise of the December 2016 Warrants the kind and amount of securities with cash or other property that the holders would have received had they exercised the December 2016 Warrants immediately prior to such fundamental transaction. At the holder's election, exercisable at any time concurrently with, or within 30 days after, the consummation of a fundamental transaction, the Company or any successor entity shall purchase the December 2016 Warrants from the holder by paying the holder an amount of cash equal to the Black-Scholes Value.

A "fundamental transaction" means any of the following: (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another person; (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions; (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock; (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property; or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another person or group of persons whereby such other person or group acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other person or other persons making or party to, or associated or affiliated with the other persons making or party to, such stock or share purchase agreement or other business combination).

"Black-Scholes Value" means the value of a December 2016 Warrant based on the Black and Scholes Option Pricing Model obtained from the "OV" function on Bloomberg, L.P. ("Bloomberg") determined as of the day of consummation of the applicable fundamental transaction for pricing purposes and reflecting (A) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the time between the date of the public announcement of the applicable fundamental transaction and December 13, 2021, (B) an expected volatility equal to the greater of 100% and the 100 day volatility obtained from the HVT function on Bloomberg as of the trading day immediately following the public announcement of the applicable fundamental transaction, (C) the underlying price per share used in such calculation shall be the sum of the price per share being offered in cash, if any, plus the value of any non-cash consideration, if any, being offered in such fundamental transaction, and (D) a remaining option time equal to the time between the date of the public announcement of the applicable fundamental transaction and December 13, 2021.

Rights as a Stockholder. Except as otherwise provided in the December 2016 Warrants or by virtue of such holder's ownership of shares of the Company's Common Stock, the holder of a December 2016 Warrant does not have the rights or privileges of a holder of Common Stock, including any voting rights, until the holder exercises the December 2016 Warrant.

April 2017 Warrants

On April 5, 2017, the Company entered into a securities purchase agreement with the purchasers set forth on the signature pages thereto, pursuant to which the Company agreed to issue and sell warrants to purchase shares of Common Stock (the "April 2017 Warrants"). On April 10, 2017, the Company issued the April 2017 Warrants.

As of September 30, 2019, April 2017 Warrants to purchase 695,312 shares of Common Stock were outstanding and exercisable.

Exercisability. The April 2017 Warrants were immediately exercisable upon issuance and will expire on April 10, 2017.

The April 2017 Warrants are exercisable, at the option of each holder, in whole or in part by delivering to the Company a duly executed exercise notice and by payment in full in immediately available funds for the number of shares of Common Stock purchased upon such exercise. Following the one year anniversary of the date the April 2017 Warrants are issued, the holder may exercise the April 2017 Warrants through a cashless exercise, in whole or in part, in which case the holder would receive upon such exercise the net number of shares of Common Stock determined according to the formula set forth in the warrant. No fractional shares of Common Stock will be issued in connection with the exercise of an April 2017 Warrant. In lieu of fractional shares, the Company will either pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price or round up to the next whole share.

Exercise Limitation. A holder will not have the right to exercise any portion of the April 2017 Warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or on election of the holder, 9.99%) of the number of shares of the Company's Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the April 2017 Warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice to the Company.

Exercise Price. The initial exercise price per share of Common Stock purchasable upon exercise of one April 2017 Warrant is $20.00 per share of Common Stock. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the Company's Common Stock.

Transferability. Subject to applicable laws, the April 2017 Warrants may be offered for sale, sold, transferred or assigned without the Company's consent. There is currently no trading market for the April 2017 Warrants and a trading market is not expected to develop.

Exchange Listing. The April 2017 Warrants are not listed on the Nasdaq Capital Market, any other national securities exchange or any other nationally recognized trading system.

Fundamental Transactions. In the event of a fundamental transaction, the holders of the April 2017 Warrants will be entitled to receive upon exercise of the April 2017 Warrants the kind and amount of securities with cash or other property that the holders would have received had they exercised the April 2017 Warrants immediately prior to such fundamental transaction.

A “fundamental transaction” means any of the following: (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another person; (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions; (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock; (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property; or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another person or group of persons whereby such other person or group acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other person or other persons making or party to, or associated or affiliated with the other persons making or party to, such stock or share purchase agreement or other business combination).

Rights as a Stockholder. Except as otherwise provided in the April 2017 Warrants or by virtue of such holder’s ownership of shares of the Company’s Common Stock, the holder of a April 2017 Warrants does not have the rights or privileges of a holder of Common Stock, including any voting rights, until the holder exercises the April 2017 Warrant.

Anti-Takeover Effects of Provisions of the Company’s Certificate of Incorporation and Delaware Law

Certain provisions of Delaware law and the Certificate of Incorporation contain provisions that could make the following transactions more difficult: acquisition of the Company by means of a tender offer; acquisition of the Company by means of a proxy contest or otherwise; or removal of the Company’s incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in the Company’s best interests, including transactions that might result in a premium over the market price for the Company’s capital stock.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of the Company to first negotiate with the Company’s board of directors. The Company believes that the benefits of increased protection of the Company’s potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure the Company outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Delaware Anti-Takeover Statute

The Company is subject to Section 203 of the DGCL, which prohibits persons deemed "interested stockholders" from engaging in a "business combination" with a publicly-held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors, such as discouraging takeover attempts that might result in a premium over the market price of the Common Stock.

Undesignated Preferred Stock

The ability to authorize undesignated Preferred Stock will make it possible for the Company's board of directors to issue Preferred Stock with voting or other rights or preferences that could impede the success of any attempt to change control of the Company. These and other provisions may have the effect of deterring hostile takeovers or delaying changes in control or management of the Company.

Elimination of Stockholder Action by Written Consent

The Certificate of Incorporation eliminates the right of stockholders to act by written consent without a meeting.

Classified Board; Election and Removal of Directors; Filling Vacancies

The Company's board of directors is divided into three classes. The directors in each class serve for a three-year term, one class being elected each year by the Company's stockholders, with staggered three-year terms. Only one class of directors will be elected at each annual meeting of the Company's stockholders, with the other classes continuing for the remainder of their respective three-year terms. At all meetings of stockholders for the election of directors, a plurality of the votes cast is sufficient to elect each director. The Certificate of Incorporation provides for the removal of any of the Company's directors only for cause and requires a stockholder vote by the holders of at least 66 2/3% of the voting power of the then outstanding voting stock with the power to vote at an election of directors. Furthermore, any vacancy on the Company's board of directors, however occurring, including a vacancy resulting from an increase in the size of the board, shall only be filled by a resolution of the board of directors unless the board of directors determines that such vacancies shall be filled by the stockholders. This system of electing and removing directors and filling vacancies may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of the Company, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Choice of Forum

The Certificate of Incorporation provides that, unless the Company consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the exclusive forum for: (a) any derivative action or proceeding brought on the Company's behalf; (b) any action asserting a claim of breach of fiduciary duty owed by any director, officer, employee, agent or stockholder of the Company to the Company or the Company's stockholders, creditors or other constituents; (c) any action asserting a claim against the Company arising pursuant to the DGCL, the Certificate of Incorporation or the Bylaws; or (d) any action asserting a claim governed by the internal affairs doctrine. Such exclusive forum provision, however, does not apply to suits brought to enforce any liability or duty created by the Securities Act or the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or any other claim for which the federal courts have exclusive jurisdiction. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the choice of forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. It could apply, however, to a suit that falls within one or more of the categories enumerated in the choice of forum provision and asserts claims under the Securities Act inasmuch as Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. There is uncertainty as to whether a court would enforce this provision with respect to claims under the Securities Act.

However, the Certificate of Incorporation does not relieve the Company of its duty to comply with federal securities laws and the rules and regulations thereunder, and the Company's stockholders will not be deemed to have waived the Company's compliance with these laws, rules and regulations. The Certificate of Incorporation also provide that any person or entity purchasing or otherwise acquiring any interest in shares of the Company's capital stock will be deemed to have notice of and consented to this choice of forum provision.

This choice of forum provision in the Certificate of Incorporation may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with the Company or its directors, officers or other employees, which may discourage such lawsuits against the Company and its directors, officers and other employees. In addition, stockholders who do bring a claim in the Court of Chancery in the State of Delaware could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near Delaware. Furthermore, the enforceability of similar choice of forum provisions in other companies' governing documents has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable.

Amendment of Charter Provisions

The amendment of any of the above provisions in the Certificate of Incorporation, except for the provision making it possible for the Company's board of directors to issue undesignated Preferred Stock, would require approval by a stockholder vote by the holders of at least 66 2/3% of the voting power of the then outstanding voting stock.

The provisions of the DGCL and the Certificate of Incorporation could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of the Common Stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the Company's management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Exhibit 10.29

Sublease Agreement

This Commercial Sublease (this "Sublease") is made effective as of March 12, 2019, by and between StartUptown dba Avenu ("Tenant"), and NeuBase Therapeutics Inc. ("Subtenant"). Tenant has previously entered into a lease agreement with Carnegie Mellon University ("Landlord") dated March 12, 2019 (the "Prime Lease"), a copy of which is attached as an exhibit to this Sublease. Tenant now desires to sublet the leased property to Subtenant and Subtenant desires to sublet the leased property from Tenant. Therefore, the parties agree as follows:

PREMISES. Tenant, in consideration of the sublease payments provided in this Agreement, sublets to Subtenant 880 rentable square feet, identified as such laboratory and office space listed in Exhibit A attached hereto, located on the third floor of 700 Technology Drive, Pittsburgh, Pennsylvania 15219 (the "Premises") and known as Landlord's Pittsburgh, Pennsylvania, university campus as the Pittsburgh Technology Center.

TERM AND POSSESSION. Subtenant will sublease the Premises for a term commencing on April 1, 2019 (the "Commencement Date") and ending one (1) year from the Commencement Date (the "Initial Sublease Term"), or at Subtenant's one-time option, for an additional period of up to six (6) successive months following the completion of the Initial Sublease Term (the "Extended Sublease Term"), provided that Subtenant has given Tenant written notice of its intention to exercise such option at least three (3) months prior to the end of the Initial Sublease Term and, if the said written notice has been provided by Subtenant in accordance with the foregoing.

SUBLEASE PAYMENTS. Subtenant shall pay to Tenant sublease payments of 2,531.73 per month, payable in advance on the first day of each month, for a total sublease payment of 30,380.76. Sublease payments shall be made to Tenant at c/o InnovatePGH, 3710 Forbes Avenue, 2nd Floor, Pittsburgh, Pennsylvania 15213, which may be changed from time to time by Tenant.

Subtenant shall pay for all utilities used or consumed at the Demised Premises during the term of this Agreement as currently obligated by the Tenant under the Prime Lease. The utilities shall be paid directly to the utility company if separately metered; otherwise, the utilities shall be prorated by Tenant in a fair and equitable manner as mutually agreed to by Tenant and Subtenant and be billed to Subtenant at the same rates as billed to Tenant by the utility company for payment to Tenant. The bills shall be due and payable within ten days of receipt.

DEFAULTS. Subtenant shall be in default of this Sublease if Subtenant fails to fulfill any lease obligation or term by which Subtenant is bound. Subject to any governing provisions of law to the contrary, if Subtenant fails to cure any financial obligation within 5 days (or any other obligation within 10 days) after written notice of such default is provided by Landlord to Subtenant, Landlord may take possession of the Premises without further notice (to the extent permitted by law), and without prejudicing Landlord's rights to damages. In the alternative, Landlord may elect to cure any default and the cost of such action shall be added to Subtenant's financial obligations under this Sublease. Subtenant shall pay all costs, damages, and expenses (including reasonable attorney fees and expenses) suffered by Landlord by reason of Subtenant's defaults. All sums of money or charges required to be paid by Subtenant under this Sublease shall be additional rent, whether or not such sums or charges are designated as "additional rent". The rights provided by this paragraph are cumulative in nature and are in addition to any other rights afforded by law.

SECURITY DEPOSIT. At the time of the signing of this Sublease, Subtenant shall pay to Landlord, in trust, a security deposit of 2,531.73 to be held and disbursed for Subtenant damages to the Premises or other defaults under this Sublease (if any) as provided by law.

CUMULATIVE RIGHTS. The rights of the parties under this Sublease are cumulative, and shall not be construed as exclusive unless otherwise required by law.

NON-SUFFICIENT FUNDS. Subtenant shall be charged $35.00 for each check that is returned to Landlord for lack of sufficient funds.

INSURANCE. Subtenant shall procure and maintain during the term, at its own expense, the following types of insurance with limits of liability shown below with insurance carriers that have an A.M. Best rating of at least an "A-" or similar rating and that are acceptable to Landlord and Tenant:

(i) Commercial General Liability— But not limited to, products, contractual, completed operations, personal injury, and medical payments;	$2,000,000 General Aggregate $2,000,000 Products-Completed/Operations $2,000,000 Personal & Adv. Inj. $2,000,000 Each Occurrence $100,000 Fire Damage Limit $10,000 Medical Expense
(ii) Automobile Liability, including for all owned, hired car and non-owned autos;	$1,000,000 Per Accident
(iii) Workers' Compensation	Statutory
and Employer's Liability	$1,000,000 Each Accident $1,000,000 Disease–Policy Limit $1,000,000 Disease–Each Employee
(iv) Excess/Umbrella Liability	$4,000,000 Occurrence/Aggregate

Subtenant agrees to name Tenant and Landlord as an additional insured on policies listed above as items (i), (ii) and (iv). If Subtenant fails to maintain such insurance as described above, Landlord or Tenant shall have the right, but not the obligation, to purchase such insurance at Subtenant's expense.

Subtenant agrees to apply its insurance or self-insurance on a "primary" basis with respect to any and all insurance coverages that Landlord may have.

Subtenant shall send/fax to Landlord and Tenant one (1) current Certificate of Insurance, appropriately identified with the address of the Building and Premises in connection with the execution of this Lease to the address set forth below, and thereafter, upon renewal of the required insurance policies.

WAIVER OF RIGHTS. Each of Tenant and Subtenant agrees to, and does hereby, waive all rights of recovery and causes of action against the other, their respective agents and employees, and all persons claiming through or under the other, relating to loss of business, business interruption or loss of rentals resulting from any damage or destruction to the Demised Premises or any of Subtenant's property contained therein, notwithstanding that any such damage or destruction may be due to the negligence of Tenant or Subtenant, their respective agents or employees. Tenant and Subtenant also waive all rights of recovery and causes of action against Lessor for loss of business, business interruption or loss of rentals, resulting from any such damage or destruction, notwithstanding that such damage or destruction may be due to the negligence of Tenant or Subtenant, their respective agents and employees.

NOTICE. Notices under this Sublease shall not be deemed valid unless given or served in writing and forwarded by mail, postage prepaid, addressed as follows to every interested party:

TENANT:

StartUptown dba Avenu
544 Miltenberger Street
Pittsburgh, Pennsylvania 15219

SUBTENANT:

NeuBase Therapeutics Inc.
213 Smithfield Street
Pittsburgh, Pennsylvania 15222

LANDLORD:

Carnegie Mellon University
5000 Forbes Avenue
Pittsburgh, Pennsylvania 15213

Such addresses may be changed from time to time by any party by providing notice to the other interested parties as described above.

GOVERNING LAW. This Sublease shall be construed in accordance with the laws of the Commonwealth of Pennsylvania.

LANDLORD'S CONSENT. The Prime Lease requires the prior written consent of Landlord to any subletting of the Premises.

INCORPORATION OF PRIME LEASE. This Sublease is subject to all of the terms of the Prime Lease with the same force and effect as if each provision of the Prime Lease were included in this Sublease, except as otherwise provided in this Sublease. All of the obligations and rights of Tenant under the Prime Lease shall be binding upon Subtenant. All of the obligations of Landlord under the Prime Lease shall inure to the benefit of Subtenant. It is the intent of the parties that, except as otherwise provided in this Sublease, the relationship between Tenant and Subtenant shall be governed by the various provisions of the Prime Lease as if those provisions were included in this Sublease in full, except that the terms "Landlord," "Tenant" and "Lease" as used in the Prime Lease, shall instead refer to, respectively, "Tenant," "Subtenant" and "Sublease." The Subtenant herein executes this Sublease with the express acknowledgement that Subtenant has read, reviewed, understands and agrees to comply with all obligations, rights, limitation and responsibilities contained in the Prime Lease.

TENANT

/s/ Sean C. Luther

StartUptown dba Avenu

by: Sean C. Luther

Executive Director

SUBTENANT

/s/ Dr. Dietrich Stephan

NeuBase Therapeutics Inc.

by: Dr. Dietrich Stephan

EXHIBIT A

DESCRIPTION OF PREMISES

Certain suites located on the 3rd floor the Pittsburgh Technology Center, 700 Technology Drive, Pittsburgh, PA 15213, designated as: Room 3316 comprised of 621 SF and Room 3321 comprised of 187 SF.

Exhibit 10.30

AMENDMENT NO. 1 TO SUBLEASE AGREEMENT

This Amendment No. 1 to Sublease Agreement (this "Amendment") is made and entered into this 3rd day of May 2019, with an effective date of June 1, 2019, by and between StartUptown dba Avenu ("Tenant"), and NeuBase Therapeutics Inc. ("Subtenant"). Tenant has previously amended its lease agreement with Carnegie Mellon University ("Landlord") dated May 3, 2019 (the "Prime Lease"), a copy of which is attached as an exhibit to this Sublease.

WITNESSETH

WHEREAS, Tenant and Subtenant entered into that certain Lease Agreement, dated as of March 12, 2019 (the "Sublease"); and

WHEREAS, by this Amendment, the parties desire to amend the Sublease as provided herein. NOW THEREFORE, in consideration of the mutual covenants contained herein and intending to be legally bound hereby, the parties agree as follows:

1. The first sentence of the PREMISES section is amended by deleting "808 rentable square feet" and replacing it with "1,443 rentable square feet."

2. The first sentence of the SUBLEASE PAYMENTS section of the Sublease is amended by deleting "2,531.73" and replacing it with "$4,521.40".

3. Exhibit A to the Sublease is hereby deleted and replaced with Exhibit A attached hereto.

4. Except as otherwise provided herein, the terms and conditions of the Sublease shall remain in full force and effect.

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment as of the day and year first set forth above.

TENANT

/s/ Sean C. Luther
StartUptown dba Avenu
by: Sean C. Luther
Executive Director

SUBTENANT

/s/ Dr. Dietrich Stephan
NeuBase Therapeutics Inc.
by: Dr. Dietrich Stephan

EXHIBIT A

DESCRIPTION OF PREMISES

Certain suites located on the 3rd floor the Pittsburgh Technology Center, 700 Technology Drive, Pittsburgh, PA 15213, designated as: Room 3316 comprised of 621 SF, Room 3321 comprised of 187 SF, Room 3323 comprised of 154 SF, Room 3325 comprised of 152 SF, and Room 3327 comprised of 329 SF.

Pittsburgh Technology Center
Floor 3

Exhibit 10.31

AMENDMENT NO. 2 TO SUBLEASE AGREEMENT

This Amendment No. 2 to Sublease Agreement (this "Amendment") is made and entered into this 29nd day of July 2019, with an effective date of August 1, 2019, by and between StartUptown dba Avenu ("Tenant"), and NeuBase Therapeutics Inc. ("Subtenant"). Tenant has previously amended its lease agreement with Carnegie Mellon University ("Landlord") dated May 3, 2019 (the "Prime Lease"), a copy of which is attached as an exhibit to this Sublease.

WITNESSETH

WHEREAS, Tenant and Subtenant entered into that certain Lease Agreement, dated as of March 12, 2019 (the "Sublease"); and

WHEREAS, by this Amendment, the parties desire to amend the Sublease as provided herein.

NOW THEREFORE, in consideration of the mutual covenants contained herein and intending to be legally bound hereby, the parties agree as follows;

1. The first sentence of the PREMISES section is amended by deleting "1,443 rentable square feet" and replacing it with "2,197 rentable square feet."

2. The first sentence of the SUBLEASE PAYMENTS section of the Sublease is amended by deleting "4,521.40" and replacing it with "$6.883.93".

3. Exhibit A to the Sublease is hereby deleted and replaced with Exhibit A attached hereto.

4. Except as otherwise provided herein, the terms and conditions of the Sublease shall remain in full force and effect.

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment as of the day and year first set forth above.

TENANT

/s/ Sean C. Luther
Start Uptown dba Avenu
by: Sean C. Luther
Executive Director

SUBTENANT

/s/ Dr. Dietrich Stephan
NeuBase Therapeutics Inc.
by: Dr. Dietrich Stephan

EXHIBIT A

DESCRIPTION OF PREMISES

Certain suites located on the 3rd floor of the Pittsburgh Technology Center, 700 Technology Drive, Pittsburgh, PA 15213, designated as: Room 3316 comprised of 621 SF, Room 3321 comprised of 187 SF, Room 3323 comprised of 154 SF, Room 3325 comprised of 152 SF, Room 3327 comprised of 329 SF, and Room 3415 comprised of 601 SF;

And certain suites located on the 4th floor designated as: Room 4315 comprised of 153 SF.

Pittsburgh Technology Center
Floor 3

Pittsburgh Technology Center
Floor 4

Exhibit 21.1

List of Subsidiaries of NeuBase Therapeutics, Inc.

1. NeuBase Corporation (incorporated in Delaware)
2. Ohr Opco, Inc. (incorporated in Delaware)
3. Ohr Pharma, LLC (organized in Delaware)

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the registration statements on Form S3 (File Nos. 333-220487 and 333-233767) and Form S-8 (File Nos. 333-215382 and 333-233346) of Neubase Therapeutics, Inc. and subsidiaries of our report, which includes an explanatory paragraph relating to the Company's ability to continue as a going concern, dated January 10, 2020 with respect to the consolidated financial statements of Neubase Therapeutics, Inc. and subsidiaries as of September 30, 2019 and for the year then ended, included in this Annual Report on Form 10-K of Neubase Therapeutics, Inc. for the year ended September 30, 2019.

/s/ CohnReznick LLP

Roseland, New Jersey
January 10, 2020

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-3 (File Nos. 333-220487 and 333-233767) and Form S-8 (File Nos. 333-215382 and 333-233346) of our report dated March 7, 2019 with respect to the audited consolidated financial statements of NeuBase Therapeutics, Inc. as of September 30, 2018 and for the period from August 28, 2018 (inception) to September 30, 2018. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ MaloneBailey, LLP
www.malonebailey.com
Houston, Texas
January 10, 2020

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Dietrich Stephan, Ph.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of NeuBase Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: January 10, 2020

By: /s/ Dietrich Stephan, Ph.D.
Dietrich Stephan, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Sam Backenroth, certify that:

1. I have reviewed this Annual Report on Form 10-K of NeuBase Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: January 10, 2020

By: /s/ Sam Backenroth
Sam Backenroth
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of NeuBase Therapeutics, Inc. (the "Company") for the period ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to their knowledge that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Dietrich Stephan, Ph.D.
Dietrich Stephan, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

January 10, 2020

By: /s/ Sam Backenroth
Sam Backenroth
Chief Financial Officer
(Principal Financial and Accounting Officer)

January 10, 2020

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Report, is not deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.