
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

or

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

For the transition period from _____ to _____

Commission file number 000-13789

ADHERA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
State or Other Jurisdiction
of Incorporation or Organization

11-2658569
(I.R.S. Employer
Identification No.)

8000 Innovation Parkway, Baton Rouge, LA 70820
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (919) 518-3748

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

Title of each class	Trading Symbol	Name of each exchange on which registered
-	-	-

Securities registered pursuant to Section 12(g) of the Act:
Common stock, par value \$0.006 per share

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒
Emerging growth company	☐		

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

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

The registrant had 11,630,709 shares of common stock outstanding as of April 7, 2021. The aggregate market value of the common stock held by non-affiliates of the registrant as of June 30, 2020 was approximately \$0.72 million as computed by reference to the closing price of such common stock on the OTC Markets on such date.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and regulations promulgated thereunder. These forward-looking statements

reflect our current views with respect to future events or our financial performance, and involve certain known and unknown risks, uncertainties and other factors, including those identified below, those discussed in Item 1A of this report under the heading “Risk Factors,” and those discussed in our other filings with the Securities and Exchange Commission, which may cause our or our industry’s actual or future results, levels of activity, performance or achievements to differ materially from those expressed or implied by any forward-looking statements or from historical results. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in the Private Securities Litigation Reform Act. Forward-looking statements include information concerning our possible or assumed future results of operations and statements preceded by, followed by, or that include the words “may,” “will,” “could,” “would,” “should,” “believe,” “expect,” “plan,” “anticipate,” “intend,” “estimate,” “predict,” “potential” or similar expressions.

Forward-looking statements are inherently subject to risks and uncertainties, many of which we cannot predict with accuracy and some of which we might not even anticipate. Although we believe that the expectations reflected in such forward-looking statements are based upon reasonable assumptions at the time made, we can give no assurance that such expectations will be achieved. Future events and actual results, financial and otherwise, may differ materially from the results discussed in the forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements. We undertake no obligation to publicly update or revise any forward-looking statements after the date of this Annual Report on Form 10-K or to conform them to actual results, new information, future events or otherwise, except as otherwise required by securities and other applicable laws.

The following factors, among others, could cause our or our industry’s future results to differ materially from historical results or those anticipated:

- our ability to obtain additional funding for our company, whether pursuant to a capital raising transaction arising from the sale of our securities, a strategic transaction or otherwise;
- our ability to satisfy our disclosure obligations under the Securities Exchange Act of 1934, as amended, and to maintain the registration of our common stock thereunder; and
- our ability to attract and retain qualified officers, directors, employees and consultants as necessary.

These factors are the important factors of which we are currently aware that could cause actual results, performance or achievements to differ materially from those expressed in any of our forward-looking statements. We operate in a continually changing business environment, and new risk factors emerge from time to time. Other unknown or unpredictable factors also could have material adverse effects on our future results, performance or achievements. We cannot assure you that projected results or events will be achieved or will occur.

PART I

ITEM 1. BUSINESS

Overview

Adhera Therapeutics, Inc. and its wholly-owned subsidiaries, MDRNA Research, Inc. (“MDRNA”), Cequent Pharmaceuticals, Inc. (“Cequent”), Atossa Healthcare, Inc. (“Atossa”), and IThenaPharma, Inc. (“IThena”) (collectively “Adhera,” the “Company,” “we,” “our,” or “us”), is an emerging specialty biotech company that, to the extent that resources and opportunities become available, is strategically evaluating its focus including a return to a drug discovery and development company.

As a result, as of the date of this report, we are not engaged in any research, development or commercialization activities, and we are not generating any revenues from operations. Moreover, as of the date of this report, we do not have any personnel other than a contracted Chief Executive Officer.

Since the end of 2019, to the extent that resources have been available, we have been working with our advisors to restructure our company and to identify potential strategic transactions to enhance the value of our company as such opportunities arise, including potential transactions and capital raising initiatives involving the assets relating to our legacy RNA interference programs, as well as business combination transactions with operating companies. There can be no assurance that we will be successful at identifying any such transactions, that we will continue to have sufficient resources to actively attempt to identify such transactions, or that such transactions will be available upon terms acceptable to us or at all. If we do not complete any significant strategic transactions, or raise substantial additional capital, in the immediate future, it is likely that we will discontinue all operations and seek bankruptcy protection.

Background

On November 15, 2016, Adhera entered into an Agreement and Plan of Merger with IThenapharma, Inc., a Delaware corporation, IThena Acquisition Corporation, a Delaware corporation and a wholly-owned subsidiary of IThena (“Merger Sub”), and a representative of the stockholders of IThena (the “Merger Agreement”), pursuant to which, among other things, Merger Sub merged with and into IThena, with IThena surviving as a wholly-owned subsidiary of Adhera (such transaction, the “Merger”). As a result of the Merger, the former holders of IThena common stock immediately prior to the completion of the Merger owned approximately 65% of the issued and outstanding shares of Adhera common stock immediately following the completion of the Merger.

Adhera was incorporated under the laws of the State of Delaware under the name Nastech Pharmaceutical Company on September 23, 1983, and IThena was incorporated under the laws of the State of Delaware on September 3, 2014. IThena is deemed to be the accounting acquirer in the Merger, and thus the historical financial statements of IThena will be treated as the historical financial statements of our company and will be reflected in our quarterly and annual reports for periods ending after the effective time of the Merger. Accordingly, beginning with our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, we started to report the results of IThena and Adhera and their respective subsidiaries on a consolidated basis.

Subsequent to the Merger, we executed on our strategy to become a commercial stage pharmaceutical company by acquiring Prestalia from Symplmed Pharmaceuticals LLC in June 2017. Prestalia is an FDA-approved and marketed anti-hypertensive drug. Prestalia is an FDC of perindopril arginine, which is an ACE inhibitor, and amlodipine besylate, which is a calcium-channel blocker and is indicated as a first line therapy for hypertension control. The acquisition of Prestalia transitioned our company from a clinical stage company to a commercial organization. We re-introduced Prestalia into the U.S. market in June 2018, with continued promotion through December 2019, at which time we terminated our business operations, including the commercialization of Prestalia.

Prestalia was developed in coordination with Les Laboratoires, Servier, a French pharmaceutical conglomerate, that sells the formulation outside the United States under the brand names Coveram® and/or Viacor®. Prestalia was approved by the U.S. Food and Drug Administration (“FDA”) in January 2015, and was distributed through our patented DyrctAcess platform.

On January 4, 2021, Servier terminated its licensing agreement with us and all rights related to future commercialization activities related to the product.

Need for Future Financing

We will require substantial additional funds on an immediate basis to continue our business operations. We have, in the past, raised additional capital to supplement our commercialization, clinical and pre-clinical development and operational expenses. We will need to raise additional funds through equity financing, debt financing, strategic alliances, or other sources, which may result in significant further dilution in the equity ownership of our shares or result in further encumbrances being placed on our assets. There can be no assurance that additional financing will be

available when needed or, if available, that it can be obtained on commercially reasonable terms, or that it will be sufficient for us to successfully engage in any of our planned business operations, including re-starting the drug development and discovery programs relating to our legacy RNA interference assets. If we are not able to obtain additional financing on a timely basis as required or generate significant capital from the out-licensing and/or divestiture of existing assets, we will not be able to meet our other obligations as they become due and will be forced to scale down or even cease our operations altogether.

Partnering and Licensing Agreements

Les Laboratoires Servier

As a result of the Asset Purchase Agreement that we entered into with Symplmed Pharmaceuticals LLC in June 2017, Symplmed Pharmaceuticals assigned to us all of its rights and obligations under that certain Amended and Restated License and Commercialization Agreement by and between Symplmed Pharmaceuticals and Les Laboratoires Servier (“Servier”) dated January 2012. Pursuant to the License Agreement, we have an exclusive license from Servier to manufacture, have manufactured, develop, promote, market, distribute and sell Prestalia in the U.S. (and its territories and possessions) in consideration of the regulatory and sales-based milestone payments, and royalty payments based on net sales, described therein. As per the License Agreement, as amended, Servier has the right to terminate the License Agreement in various circumstances, including, without limitation, if net sales of Prestalia are below \$1 million for two successive calendar quarters beginning after June 30, 2020. On January 4, 2021, Servier terminated the agreement for the marketing and commercialization of Prestalia.

Autotelic LLC

On November 15, 2016, we entered into a License Agreement with Autotelic LLC pursuant to which (A) we licensed to Autotelic LLC certain patent rights, data and know-how relating to FAP and nasal insulin, for human therapeutics other than for oncology-related therapies and indications, and (B) Autotelic LLC licensed to us certain patent rights, data and know-how relating to IT-102 and IT-103, in connection with individualized therapy of pain using a non-steroidal anti-inflammatory drug and an anti-hypertensive without inducing intolerable edema, and treatment of certain aspects of proliferative disease, but not including rights to IT-102/IT-103 for TDM guided dosing for all indications using an Autotelic Inc. TDM Device. We also granted a right of first refusal to Autotelic LLC with respect to any license by us of the rights licensed by or to us under the License Agreement in any cancer indication outside of gastrointestinal cancers. As per the Omnibus Settlement Agreement that we entered into on October 1, 2018 with Dr. Trieu, Autotelic LLC and certain other parties affiliated with Dr. Trieu, the License Agreement shall continue, provided that Autotelic LLC shall be licensee and have a license to, without representation or warranty, nasal apomorphine and nasal scopolamine and related intellectual property in addition to nasal insulin, and Autotelic LLC shall not be a licensee or have a license to FAP or CEQ508 and related intellectual property.

Hongene Biotechnology

In September 2015, Adhera entered into a license agreement with Hongene, a leader in process development and analytical method development of oligonucleotide therapeutics, regarding the development and supply of certain oligonucleotide constructs using our CRN technology. To date, there has been minimal activity under this agreement. However, as per the terms of the agreement, we could receive double digit percentage royalties on the sales of research reagents using our CRN technology.

Rosetta

On April 1, 2014, we entered into a strategic alliance with Rosetta to identify and develop microRNA- (“miRNA”) based products designed to diagnose and treat various neuromuscular diseases and dystrophies. Under the terms of the alliance, Rosetta will apply its industry leading miRNA discovery expertise for the identification of miRNAs involved in the various dystrophy diseases. If the miRNA is determined to be correlative to the disease,

Rosetta may further develop the miRNA into a diagnostic for patient identification and stratification. If the miRNA is determined to be involved in the disease pathology and represents a potential therapeutic target, Adhera may develop the resulting miRNA-based therapeutic for clinical development. The alliance is exclusive as it relates to neuromuscular diseases and dystrophies, with both companies free to develop and collaborate outside this field both during and after the terms of the alliance.

Novartis

On August 2, 2012, we and Novartis entered into a worldwide, non-exclusive License Agreement for the CRN technology for the development of both single and double-stranded oligonucleotide therapeutics. Novartis made a \$1.0 million one-time payment for the non-exclusive license. In addition, in March 2009, we granted to Novartis a worldwide, non-exclusive, irrevocable, perpetual, royalty-free, fully paid-up license, with the right to grant sublicenses, to the DiLA2-based siRNA delivery platform in consideration of a one-time, non-refundable fee of \$7.25 million. Novartis may terminate this agreement immediately upon written notice.

Novosom

On July 27, 2010, we acquired the intellectual property of Novosom for SMARTICLES. As per the terms of the acquisition agreement (the “Original Purchase Agreement”), we were required to pay to Novosom an amount equal to 30% of the value of each upfront (or combined) payment actually received in respect of the license of liposomal-based delivery technology or related product or disposition of the liposomal-based delivery technology by us, up to \$3.3 million, which amount was to be paid in shares of common stock, or a combination of cash and shares of common stock, at our discretion. On September 8, 2017, we entered into an Intellectual Property Purchase Agreement (the “IP Purchase Agreement”) with Novosom pursuant to which we sold to Novosom substantially all of our intellectual property estate relating to SMARTICLES (the “Smarticles IP”), including that acquired pursuant to the Original Purchase Agreement, for an aggregate purchase price of \$1.00. As per an amendment to the IP Purchase Agreement, we assigned to Novosom those agreements that we entered into with third parties pursuant to which we provided to such third parties certain licenses and rights with respect to the Smarticles IP, including the right to receive milestone and royalty payments, if any. Novosom made to us a cash payment in the amount of \$45,000 in connection with the amendment to the IP Purchase Agreement.

Valeant Pharmaceuticals

On March 23, 2010, we acquired intellectual property related to the CRN chemistry from Valeant Pharmaceuticals North America (“Valeant”). Subject to meeting certain milestones triggering the obligation to make any such payments, we may be obligated to make a product development milestone payment of \$5.0 million and \$2.0 million within 180 days of FDA approval of an NDA for our first and second CRN related product, respectively. To date, we have not made any such milestone payments but have milestone obligations of \$0.1 million based on CRN licenses to date. Valeant is entitled to receive earn-outs based upon a percentage in the low single digits of future commercial sales and earn-outs based upon a percentage in the low double digits of future revenue from sublicensing. We are required to pay Valeant an annual amount equal to \$50,000 per assigned patent which shall be creditable against other payment obligations. The term of our financial obligations under the agreement shall end, on a country-by-country basis, when there no longer exists any valid claim in such country. We may terminate the agreement upon 30-day notice, or upon 10-day notice in the event of adverse results from clinical studies.

Proprietary Rights and Intellectual Property

We have relied primarily on patents and contractual obligations with employees and third parties to protect our proprietary rights. We have sought, and, to the extent that we continue our business operations, intend to continue to seek, appropriate patent protection for important and strategic components of our proprietary technologies by filing patent applications in the U.S. and certain foreign countries. To date, the U.S. and non-U.S. patent applications that we have filed, and the patents that have been granted to us, relate to our legacy intranasal and RNA interference

programs. As noted elsewhere in this report, we are in the process of evaluating the path forward for such programs, including seeking options to continue certain programs or to divest assets. There can be no assurance that any of our patents will be guaranteed protection or market exclusivity for our products and product candidates, and to the extent that we do not properly maintain (including paying any required fees) such patents, it is possible that any protection provided to us will be impaired or lost altogether.

We also use license agreements both to access external technologies and to convey certain intellectual property rights to others. To the extent that we continue our business operations, our financial success will be dependent in part on our ability to obtain (and maintain) commercially valuable patent claims and to protect our intellectual property rights and to operate without infringing upon the proprietary rights of others.

Further, as discussed elsewhere in this report, we had licensed rights to our FDA-approved product, Prestalia, from Les Laboratoires Servier as a result of our acquisition of assets from Symplmed Pharmaceuticals in June 2017. The patents listed in the FDA Orange Book as having claims covering Prestalia, U.S. Patent No. 6,696,481 and 7,846,961, expire in 2023 and 2029, respectively. On January 4, 2021, the Servier terminated the licensing for the preceding patents. We also hold a patent to our DyrctAcess technology platform (U.S. Patent No. 8,738,398).

Sales and Marketing

We terminated our commercial activities related to Prestalia in 2019. Sales and marketing activities in 2020, were primarily related to regulatory activities to maintain the Prestalia NDA.

Competition

The biopharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. The key competitive factors affecting the success of any products and product candidates that we may develop or acquire, to the extent that we may continue to engage in the biopharmaceutical industry, are their efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors. While we believe that our technology, knowledge and experience provide us with certain competitive advantages, we face potential competition from many different sources, including major and minor pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and public and private research institutions. Our products, and any product candidates that we successfully develop and/or acquire, and later commercialize, will compete with existing therapies and new therapies that may become available in the future.

We anticipate that many of the companies against which we may compete in the future will have significantly greater financial and other resources and expertise in research and development, manufacturing, product acquisition, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the biopharmaceutical industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete, or may compete, with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring technologies and products complementary to, or that may be necessary for, our programs.

The commercial opportunity for any product candidates that we may acquire and/or develop could be reduced or eliminated if our competitors develop and commercialize drugs or therapies that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we may acquire or develop. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic drugs.

Government Regulation

Government authorities in the U.S. and other countries extensively regulate the research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing, among other things, of drugs and pharmaceutical products. To the extent that we continue to engage in the biopharmaceutical industry, of which there can be no assurance, all of the products that we anticipate seeking to develop and/or commercialize are expected to be regulated as drug products.

In the U.S., the FDA regulates drug products under the Federal Food, Drug and Cosmetic Act (the “FDCA”), and other laws within the Public Health Service Act. Failure to comply with applicable U.S. requirements, both before and after approval, may subject us to administrative and judicial sanctions, such as a delay in approving or refusal by the FDA to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, and/or criminal prosecutions. Before any drug products that we may develop and/or acquire are marketed, they must be approved by the FDA. The steps required before a drug product is approved by the FDA include: (1) pre-clinical laboratory, animal, and formulation tests; (2) submission to the FDA of an Investigational New Drug Application (“IND”) for human clinical testing, which must become effective before human clinical trials may begin; (3) adequate and well-controlled clinical trials to establish the safety and effectiveness of the product for each indication for which approval is sought; (4) submission to the FDA of a New Drug Application (“NDA”); (5) satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug product is produced to assess compliance with cGMP and FDA review; and finally (6) approval of an NDA.

Pre-clinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. The results of the pre-clinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions, such as the conduct of the trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. There can be no assurance that submission of an IND will result in FDA authorization to commence clinical trials. Once an IND is in effect, each clinical trial to be conducted under the IND must be submitted to the FDA, which may or may not allow the trial to proceed.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified physician-investigators and healthcare personnel. Clinical trials are typically conducted in three defined phases, but the phases may overlap or be combined. Phase 1 usually involves the initial administration of the investigational drug or biologic product to healthy individuals to evaluate its safety, dosage tolerance and pharmacodynamics. Phase 2 usually involves trials in a limited patient population, with the disease or condition for which the test material is being developed, to evaluate dosage tolerance and appropriate dosage; identify possible adverse side effects and safety risks; and preliminarily evaluate the effectiveness of the drug or biologic for specific indications. Phase 3 trials usually further evaluate effectiveness and test further for safety by administering the drug or biologic candidate in its final form in an expanded patient population. To the extent that we engage in any product development activities, our product development partners, the FDA, or we may suspend clinical trials, if any, at any time on various grounds, including any situation where we or our partners believe that patients are being exposed to an unacceptable health risk or are obtaining no medical benefit from the test material.

Assuming successful completion of the required clinical testing, the results of the pre-clinical trials and the clinical trials, together with other detailed information, including information on the manufacture and composition of the product, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. Before approving an application, the FDA will usually inspect the facilities where the product is manufactured and will not approve the product unless cGMP compliance is satisfactory. If the FDA determines the NDA is not acceptable, the FDA may outline the deficiencies in the NDA and often will request additional information. If the FDA approves the NDA, certain changes to the approved product, such as adding new indications, manufacturing changes or additional labeling claims are subject to further FDA review and approval. The testing and approval process require substantial time, effort, and financial resources, and we cannot be sure that any approval of any products that we develop and/or acquire will be granted on a timely basis, if at all.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug for this type of disease or condition will be recovered from sales in the U.S. for that drug. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same drug for the same indication, except in very limited circumstances, for seven years. The FDA granted orphan drug designation to CEQ508 for the treatment of FAP in December 2010. We are evaluating the best path forward to re-start development activities regarding CEQ508, and evaluating options for our other programs relating to RNA interference.

In addition, regardless of the type of approval, to the extent that we continue to engage in the biopharmaceutical industry, we and our partners will be required to comply with a number of FDA requirements both before and after approval with respect to any products that we may develop, acquire or commercialize. For example, we and our partners will be required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain requirements concerning advertising and promotion for products. In addition, quality control and manufacturing procedures must continue to conform to cGMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to expend time, money and effort in all areas of regulatory compliance, including production and quality control to comply with cGMP. In addition, discovery of problems, such as safety problems, may result in changes in labeling or restrictions on a product manufacturer or NDA holder, including removal of the product from the market.

In addition to FDA regulations for the marketing of pharmaceutical products, there are various other state and federal laws that may restrict business practices in the biopharmaceutical industry. These include the following:

- The federal Medicare and Medicaid Anti-Kickback laws, which prohibit persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- Other Medicare laws, regulations, rules, manual provisions and policies that prescribe the requirements for coverage and payment for services performed by our customers, including the amount of such payment;
- The federal False Claims Act which imposes civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government;
- The Foreign Corrupt Practices Act ("FCPA"), which prohibits certain payments made to foreign government officials;
- State and foreign law equivalents of the foregoing and state laws regarding pharmaceutical company marketing compliance, reporting and disclosure obligations;
- The Patient Protection and Affordable Care Act ("ACA"), which among other things changes access to healthcare products and services; creates new fees for the pharmaceutical and medical device industries; changes rebates and prices for health care products and services; and requires additional reporting and disclosure; and
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), which imposes requirements on certain types of people and entities relating to the privacy, security, and transmission of individually identifiable health information, and requires notification to affected

individuals and regulatory authorities of certain breaches of security of individually identifiable health information;

If our operations are found to be in violation of any of these laws, regulations, rules or policies or any other law or governmental regulation, or if interpretations of the foregoing change, we may be subject to civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment or restructuring of our operations.

To the extent that any of the products that we develop and/or acquire are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals. None of our products were ever sold outside the United States.

Coverage and Reimbursement

To the extent that we continue to engage in the biopharmaceutical industry, the commercial success of our product candidates and our ability to commercialize any approved product candidates successfully will depend in part on the extent to which governmental authorities, private health insurers and other third-party payers provide coverage for and establish adequate reimbursement levels for our product candidates. In the United States, government authorities and third-party payers are increasingly imposing additional requirements and restrictions on coverage, attempting to limit reimbursement levels or regulate the price of drugs and other medical products and services, particularly for new and innovative products and therapies, which often has resulted in average selling prices lower than they would otherwise be. For example, in the United States, federal and state governments reimburse covered prescription drugs at varying rates generally below average wholesale price. Federal programs also impose price controls through mandatory ceiling prices on purchases by federal agencies and federally funded hospitals and clinics and mandatory rebates on retail pharmacy prescriptions paid by Medicaid and Tricare. These restrictions and limitations influence the purchase of healthcare services and products. Legislative proposals to reform healthcare or reduce costs under government programs may result in lower reimbursement for our product candidates or exclusion of our product candidates from coverage. Moreover, the Medicare and Medicaid programs increasingly are used as models for how private payers and other governmental payers develop their coverage and reimbursement policies.

In addition, the increased emphasis on managed healthcare in the United States will put additional pressure on product pricing, reimbursement and utilization, which, to the extent that we are commercializing products, may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, competition within therapeutic classes, availability of generic equivalents, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, coverage and reimbursement policies and pricing in general. The cost containment measures that healthcare payers and providers are instituting and any healthcare reform implemented in the future could significantly reduce our revenues from the sale of any approved products. We cannot provide any assurances that we will be able to obtain and maintain third-party coverage or adequate reimbursement for any products that we may acquire and/or develop.

Impact of Healthcare Reform on Coverage, Reimbursement, and Pricing

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“the MMA”) imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription, pharmacy drugs pursuant to federal regulations. Part D plans include both standalone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. In general, Part D prescription drug plan sponsors have flexibility regarding coverage of 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, with certain exceptions. 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 any products that we commercialize. However, any negotiated prices for our future products covered by a Part D prescription drug plan will likely be discounted, thereby lowering the net price realized on our sales to pharmacies. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from Medicare Part D may result in a similar reduction in payments from non-governmental payers.

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. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of any product candidates that we may acquire and/or develop. If third-party payers do not consider the product candidates that we may acquire and/or develop to be cost-effective compared to other available therapies, they may not cover our product candidates, once approved, as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The United States is considering enacting or have enacted a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to profitably sell any products that we may acquire and/or develop. Among policy makers and payers in the United States, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives, including, most recently, the Affordable Care Act (the "ACA"), which became law in March 2010 and substantially changes the way healthcare is financed by both governmental and private insurers. Among other cost containment measures, the ACA establishes an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; a new Medicare Part D coverage gap discount program; expansion of Medicaid benefits and a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program; and expansion of the 340B drug discount program that mandates discounts to certain hospitals, community centers and other qualifying providers. In the future, there may continue to be additional proposals relating to the reform of the United States healthcare system, some of which could further limit the prices we are able to charge or the amounts of reimbursement available for any product candidates that we acquire and/or develop once they are approved.

For example, members of Congress and the current presidential administration have expressed an intent to pass legislation or adopt executive orders to fundamentally change or repeal parts of the ACA. While Congress has not passed repeal legislation to date, several actions have been taken that revise and/or impact the ACA, including, without limitation, the Bipartisan Budget Act of 2018 that, among other things, amended the ACA to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." Congress may consider other legislation to replace elements of the ACA. The implications of the ACA, its possible repeal, any legislation that may be proposed to replace the ACA, or the political uncertainty surrounding any repeal or replacement legislation for our future business and financial condition, if any, are not yet clear.

The costs of prescription pharmaceuticals in the U.S. recently has also been the subject of considerable discussion in the U.S., and members of Congress and the current presidential administration have stated that they will address such costs through new legislative and administrative measures. To date, there have been several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, Congress and the current presidential administration have each indicated that it will continue to pursue new legislative and/or administrative measures to control drug costs.

Individual state legislatures have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing. Some of these measures include price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for any products we may acquire and/or develop, once approved, or put pressure on the pricing of such products.

Additionally, the continued consolidation in healthcare of insurers, providers, large healthcare delivery systems and clinical research organizations is an additional source of change and resource constraint which may impact our ability to acquire, develop and commercialize product candidates.

We cannot predict what healthcare reform initiatives may be adopted in the future. Further federal and state legislative and regulatory developments are likely, and we expect ongoing initiatives in the U.S. to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from any products that we may acquire and/or develop, and may affect our overall financial condition and ability to realize the full value of our product(s), if any, as they are developed and ultimately commercialized.

Exclusivity and Approval of Competing Products Hatch-Waxman Patent Exclusivity

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's product or a method of using the product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application ("ANDA") or 505(b)(2) NDA. Generally, an ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths, dosage form and route of administration as the listed drug and has been shown to be bioequivalent through *in vitro* or *in vivo* testing or otherwise to the listed drug. ANDA applicants are not required to conduct or submit results of preclinical or clinical tests to prove the safety or effectiveness of their drug product, other than the requirement for bioequivalence testing. 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 reference listed drug. 505(b)(2) NDAs generally are submitted for changes to a previously approved drug product, such as a new dosage form or indication.

The ANDA or 505(b)(2) NDA applicant is required to provide a certification to the FDA in the product application concerning any patents listed for the approved product in the FDA's Orange Book, except for patents covering methods of use for which the applicant is not seeking approval. Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable, or will not be infringed by the new product.

Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except when the ANDA or 505(b)(2) NDA applicant challenges a listed patent or if the listed patent is a patented method of use for which approval is not being sought. A certification that the proposed product will not infringe the already

approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or does not indicate that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA or 505(b)(2) NDA 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 application 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 after the receipt of notice of the Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, a decision in the infringement case that is favorable to the ANDA applicant or other period determined by a court.

Hatch-Waxman Non-Patent Exclusivity

Market and data exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications for competing products. The FDCA provides a five-year period of non-patent data 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 therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

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The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA, or supplement to an existing NDA or 505(b)(2) 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 or supplement. Three-year exclusivity may be awarded for changes to a previously approved drug product, such as new indications, dosages, strengths or dosage forms of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and, as a general matter, does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. 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 preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Product Liability

We currently have no product liability insurance. We believe this is appropriate for our stage of development as we currently have no commercial products. Any product liability insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have a material adverse effect on our business.

Environmental Compliance

To the extent that we begin to re-engage in research and development activities, which activities are not currently being actively pursued by us, such activities may involve the controlled use of potentially harmful biological materials as well as hazardous materials, chemicals and various radioactive compounds. We are subject to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specific waste products. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of bio-hazardous materials. The cost of compliance with these laws and regulations could be significant and may adversely

affect capital expenditures to the extent we are required to procure expensive capital equipment to meet regulatory requirements.

Employees

As of March 31, 2021, we had no employees. Our current Chief Executive Officer and services related to our accounting and financial management are being performed by independent contractors.

Company Information

We are a reporting company and are required to file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy these reports, proxy statements and other information at the SEC's Public Reference Room at 100 F Street N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 or e-mail the SEC at publicinfo@sec.gov for more information on the operation of the public reference room. Our SEC filings are also available at the SEC's website at <http://www.sec.gov>. Our Internet address is <http://www.adherathera.com>. There we make available, free of charge, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the SEC.

ITEM 1A. RISK FACTORS

Investing in our securities has a high degree of risk. Before making an investment in our securities, you should carefully consider the following risks, as well as the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties of which we are unaware or that we believe are not material at this time could also materially adversely affect our business, financial condition or results of operations. In any case, the value of our securities could decline, and you could lose all or part of your investment. See also the information contained under the heading "Cautionary Statement Regarding Forward-Looking Statements" elsewhere in this Annual Report on Form 10-K.

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Risks Relating to Our Financial Condition and Business Operations

We have terminated our business operations and are currently pursuing other opportunities to restructure our company. If we are not successful in these efforts, it is likely that we will discontinue all operations and seek bankruptcy protection.

As a result, as of the date of this report, we are not engaged in any research, development or commercialization activities, and we are no longer generating revenues from the sale of Prestalia or any other product. Moreover, as of the date of this report, we do not have any personnel other than our contracted Chief Executive Officer.

During 2020, we worked with our advisors to restructure our company and to identify potential strategic transactions to enhance the value of our company as such opportunities arise, including potential transactions and capital raising initiatives involving the assets relating to our legacy RNA interference programs, as well as business combination transactions with operating companies. There can be no assurance that we will be successful at identifying any transactions that enhance the value of our company, or that such transactions will be available upon terms acceptable to us. Further, there can be no assurance that we will engage in future business activities in the biopharmaceutical industry or any other industry. If we do not complete any significant strategic transactions, or raise substantial additional capital, in the immediate future, it is likely that we will discontinue all operations and seek bankruptcy protection.

Our current cash is not sufficient to fund our business operations beyond the date of this filing. If additional capital is not available, we may have to cease operations, or take other actions that could adversely impact our shareholders.

Our business does not generate the cash necessary to finance our operations. Although we generated revenues during 2019 through the sale of Prestalia, we have ceased selling such product, and thus are no longer generating revenues from the sale of that product or any other product. We incurred net operating losses of approximately \$2.0 million and \$11.3 million in the years ended December 31, 2020 and 2019, respectively.

To the extent that we continue to engage in the biopharmaceutical industry, we will require significant additional capital to: (i) acquire and/or develop additional FDA-approved products, and commercialize such products; (ii) fund research and development activities relating to, and obtain regulatory approval for, our current and future product candidates; (iii) protect our intellectual property; (iv) attract and retain highly-qualified personnel; (v) respond effectively to competitive pressures; and (vi) acquire complementary businesses or technologies.

To the extent that we continue to engage in the biopharmaceutical industry, our future capital needs depend on many factors, including: (i) the scope, duration and expenditures associated with research, development and commercialization efforts that we may undertake; (ii) continued scientific progress in our programs; (iii) the outcome of potential partnering or licensing transactions, if any; (iv) competing technological developments; (v) our proprietary patent position; and (vi) the regulatory approval process for our products.

We will need to raise additional funds through public or private equity offerings, debt financings or additional strategic alliances and licensing arrangements to continue our business operations. We may not be able to obtain additional financing on terms favorable to us, if at all. General market conditions, as well as market conditions for companies in our financial and business position, as well as the ongoing issue arising from the COVID-19 epidemic, may make it difficult for us to seek financing from the capital markets, and the terms of any financing may adversely affect the holdings or the rights of our stockholders. For example, if we raise additional funds by issuing equity securities, further dilution to our stockholders will result, which may substantially dilute the value of their investment. Any such equity financing may also have the effect of substantially reducing the conversion or exercise price of our outstanding convertible or exercisable securities, which could result in the issuance (or potential issuance) of a significant number of additional shares of our common stock to the extent that the aggregate conversion or exercise price of such convertible or exercisable securities remains the same. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Debt financing, if available, may involve restrictive covenants that could limit our flexibility to conduct future business activities and, in the event of insolvency, could be paid before holders of equity securities received any distribution of corporate assets. We may be required to relinquish rights to our technologies or drug candidates, or grant licenses through alliance, joint venture or agreements on terms that are not favorable to us, in order to raise additional funds. If adequate funds are not available, we may have to further delay, reduce or eliminate one or more of our planned activities with respect to our business, or terminate our operations and seek appropriate bankruptcy protection. These actions would likely reduce the market price of our common stock.

We have no history of profitability and there is a potential for fluctuation in operating results.

We have experienced significant operating losses since inception. We expect that the continued operation of our business, if at all, will cause us to continue to experience losses in the near term, particularly if we were to again engage in research and development activities. There can be no assurance that we can achieve profitability in the future. To the extent that we continue to engage in the biopharmaceutical industry, our ability to achieve profitability will depend on our ability to commercialize, acquire and develop approved pharmaceutical products, obtain necessary regulatory approvals, and manufacture, distribute, market and sell drug products. We cannot assure you of the success of any of these activities or predict if or when we will ever become profitable. These factors raise substantial doubt about our ability to continue as a going concern. See “Management’s Discussion and Analysis of Financial Condition

and Results of Operations” and “Cautionary Statement Regarding Forward-Looking Statements”, as well as the financial statements included herein.

If we are unable to raise sufficient additional capital, we may seek to merge with or be acquired by another entity, or to sell our assets to another entity, and that transaction may adversely affect our business and the value of our securities.

If we are unable to raise sufficient additional capital to continue business operations with respect to our existing assets, of which there can be no assurance, we may seek to merge or combine with, or otherwise be acquired by, another entity with a stronger cash position or product portfolio or for other reasons. There are numerous risks associated with merging, combining or otherwise being acquired, whether in whole or in part. These risks include, among others, incorrectly assessing the quality of a prospective acquirer or merger-partner, encountering greater than anticipated costs in integrating businesses, facing resistance from employees and being unable to profitably deploy the assets of the new entity. The operations, financial condition, and prospects of the post-transaction entity depend in part on our and our acquirer/merger-partner’s ability to successfully integrate the operations related to our products, product candidates, business and technologies. We may be unable to integrate operations successfully or to achieve expected cost savings, and any cost savings that are realized may be offset by losses in revenues or other charges to operations.

We may be unable to repay the indebtedness to the holders of outstanding promissory notes.

Between June 28, 2019 to August 5, 2019, we issued secured promissory notes in the aggregate principal amount of approximately \$5.7 million. We granted to the holders of such secured notes a first lien and security interest in all of the assets of our company and certain of our subsidiaries. The maturity date of the secured notes is June 28, 2020, which date may be extended for up to sixty days upon the mutual agreement of our company and the holders of a majority of the unpaid principal balance of such secured notes. Interest is payable quarterly, with the first interest payment to have been made on December 28, 2019 and with the second interest payment to have been made on March 28, 2020. We have not made the required interest payments on the secured notes. On February 5, 2020, we issued original issue discount unsecured convertible promissory notes, issued at a 10% original issue discount, for a total purchase price of \$499,950, which notes are payable on August 5, 2020. On June 26, 2020, we issued original issue discount unsecured convertible promissory notes, issued at a 10% original issue discount, for a total purchase price of \$52,500, which notes mature on December 26, 2020. On October 30, 2020, we issued original issue discount unsecured convertible promissory notes, issued at a 10% original issue discount, for a total purchase price of \$100,000, which notes mature on April 30, 2021. On January 31, 2021, we issued original issue discount unsecured convertible promissory notes, issued at a 10% original issue discount, for a total purchase price of \$52,778, which notes mature on July 31, 2021. We are in default in our obligations under the secured notes and the convertible notes, which could have a material adverse impact on our company and on our future business prospects.

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We are dependent on our key personnel, and if we are unable to retain such personnel, or to attract and retain other highly qualified personnel, then we may be unable to successfully develop our business.

Our ability to compete in the business sectors in which we anticipate conducting operations depends upon our ability to attract and retain highly qualified personnel. We are dependent on our management personnel, including Andrew Kucharchuk, our contracted Chief Executive Officer. There can be no assurance that we will be able to retain the services of Mr. Kucharchuk or of any of our other future personnel, regardless of whether or not we have entered into employment agreements with such persons. If we are unable to attract or retain qualified personnel, or if we are unable to adequately replace such personnel if we lose their services, our business could be seriously harmed. In addition, if we have to replace any of these individuals, we may not be able to replace the knowledge that they have about our operations.

If we raise capital and make strategic acquisitions of products, technologies or other businesses, we will incur a variety of costs and potential liabilities and might never realize the anticipated benefits.

We have limited experience in independently identifying acquisition candidates and successfully integrating the operations of acquisition candidates with our company. If appropriate opportunities become available, and we have sufficient resources to do so, we might attempt to acquire approved products, additional drug candidates, technologies or businesses that we believe are a strategic fit with our business. If we pursue any transaction of that sort in the future, the process of negotiating the acquisition and integrating an acquired product, drug candidate, technology or business, and the product sales and distribution networks relating to such acquired assets, might result in operating difficulties, expenditures and potential liabilities, and might require significant management attention that would otherwise be available for ongoing development of our business, whether or not any such transaction is ever consummated. Moreover, we might never realize the anticipated benefits of any acquisition. Future acquisitions could result in, among other things, dilutive issuances of equity securities, the incurrence of debt, contingent liabilities, or impairment expenses related to goodwill, and impairment or amortization expenses related to other intangible assets, which could harm our financial condition.

Failure of our internal control over financial reporting could harm our business and financial results.

Our management is responsible for establishing and maintaining effective internal control over financial reporting. Internal control over financial reporting is a process to provide reasonable assurance regarding the reliability of financial reporting for external purposes in accordance with accounting principles generally accepted in the United States. Internal control over financial reporting includes maintaining records that in reasonable detail accurately and fairly reflect our transactions; providing reasonable assurance that transactions are recorded as necessary for preparation of the financial statements; providing reasonable assurance that receipts and expenditures of our assets are made in accordance with management authorization; and providing reasonable assurance that unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements would be prevented or detected on a timely basis. Any failure to maintain an effective system of internal control over financial reporting could limit our ability to report our financial results accurately and timely or to detect and prevent fraud.

In connection with the evaluation of our internal control over financial reporting as of December 31, 2020 that was undertaken by management in connection with the preparation of our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, management determined that our lack of a sufficient complement of personnel with an appropriate level of knowledge and experience in the performance of an audit of a public company that is commensurate with our financial reporting requirements, and our overall financial and operational condition constituted a material weakness as of December 31, 2020. To remediate the foregoing material weakness, to the extent that resources permit, of which there can be no assurance, we plan to hire additional experienced accounting and other personnel to assist with filings and financial record keeping and take additional steps to improve our financial reporting systems and enhance our existing policies, procedures and controls when funds become available.

We depend on our information technology and infrastructure.

We rely on the efficient and uninterrupted operation of information technology systems to manage our operations, to process, transmit and store electronic and financial information, and to comply with regulatory, legal and tax requirements. We also depend on our information technology infrastructure for electronic communications among our personnel, contractors, consultants and vendors. System failures or outages could compromise our ability to perform these functions in a timely manner, or could result in the loss of information, which could harm our ability to conduct business or delay our financial reporting. Such failures could materially adversely affect our operating results and financial condition.

In addition, we completely depend on third parties and applications on virtualized (cloud) infrastructure to operate and support our information systems. Failure by these providers to adequately deliver the contracted services could have an adverse effect on our business, which in turn may materially adversely affect our operating results and financial condition. All information systems, despite implementation of security measures, are vulnerable to disability, failures or unauthorized access. If our information systems were to fail or be breached, such failure or breach could

materially adversely affect our ability to perform critical business functions and sensitive and confidential data could be compromised.

Our business and operations could suffer in the event of system failures.

Our internal computer systems and those of our contractors, consultants and partners are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such events could cause interruption of our operations and could result in a material disruption of our business operations. For example, to the extent that we were to engage in research and development activities, the loss of pre-clinical trial data or data from completed or ongoing clinical trials for our product candidates, if any, could result in delays in our regulatory filings and development efforts and significantly increase our costs. If any disruption or security breach were to result in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our business operations could be delayed.

We may be unable to adequately protect our information technology systems from cyber-attacks, which could result in the disclosure of confidential information, damage our reputation, and subject us to significant financial and legal exposure.

Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include wrongful conduct by hostile foreign governments, industrial espionage, the deployment of harmful malware, denial-of-service, and other means to threaten data confidentiality, integrity and availability. A successful cyber-attack could cause serious negative consequences for our company, including the disruption of operations, the misappropriation of confidential information (including patient information) and trade secrets, and the disclosure of corporate strategic plans and results. To date, we have not experienced threats to our data and information technology systems. However, although we devote resources to protect our information technology systems, we realize that cyber-attacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal or reputational harm to us, or would have a material adverse effect on our operating results and financial condition.

Risks Related to our Dependence on Third Parties

We were dependent upon Prestalia for our ability to generate revenue from the sale of products, and we are dependent upon Les Laboratoires Servier for our rights to Prestalia.

During 2019, our ability to generate revenue from the sale of drug products was dependent upon sales of Prestalia. Prestalia was the primary product to which we had rights that had been approved for sale. Sales of Prestalia accounted for all of our product revenue during 2019. Our rights to Prestalia derive from the license and commercialization agreement between our company and Les Laboratoires Servier. As per such agreement, as amended, Les Laboratoires Servier has the right in various circumstances to terminate the agreement, including, without limitation, if net sales of Prestalia are below \$1 million for two successive calendar quarters beginning after June 30, 2020. As of the end of 2019, we terminated all of our business operations with respect to the commercialization and promotion of Prestalia and are no longer selling or promoting any other products. On January 4, 2021, Les Laboratoires Servier terminated the licensing and commercialization agreement.

We may become dependent on our collaborative arrangements with third parties for a substantial portion of our revenue, and our development and commercialization activities may be delayed or reduced if we fail to initiate, negotiate or maintain successful collaborative arrangements.

To the extent that we continue to engage in pharmaceutical and biotechnology operations, we anticipate that we will be, at least in part, dependent on partners to develop and commercialize our products and to provide the regulatory compliance, sales, marketing and distribution capabilities required for the success of our business. If we fail to secure or maintain successful collaborative arrangements, we anticipate that our development and commercialization activities will be delayed, reduced or terminated, and that our revenues would be materially and adversely impacted.

The potential future milestone and royalty payments and cost reimbursements from certain of the collaboration agreements that we have entered into, or that we may enter into, could provide an important source of financing for our business activities, thereby facilitating the development and commercialization of our products. These collaborative agreements might be terminated either by us or by our partners upon the satisfaction of certain notice requirements. Our partners may not be precluded from independently pursuing competing products and drug delivery approaches or technologies. Even if our partners continue their contributions to our collaborative arrangements, of which there can be no assurance, they may nevertheless determine not to actively pursue the development or commercialization of any resulting products. Our partners may fail to perform their obligations under the collaborative arrangements or may be slow in performing their obligations. In addition, our partners may experience financial difficulties at any time that could prevent them from having available funds to contribute to these collaborations. If our collaborators fail to conduct their commercialization, regulatory compliance, sales and marketing or distribution activities successfully and in a timely manner, or if they terminate or materially modify their agreements with us, the development and commercialization of one or more product candidates could be delayed, curtailed or terminated.

We will rely on third parties to conduct clinical trials, and those third parties may not perform satisfactorily, including failing to meet established timelines for the completion of such clinical trials.

If we move forward with any research and development activities with respect to our current and future development assets, we anticipate that we will be dependent on contract research organizations, third-party vendors and investigators for performing or managing pre-clinical testing and clinical trials related to drug discovery and development efforts. These parties will not be employed by us or our partners, and neither we nor our partners will be able to control the amount or timing of resources that they devote to our programs. If they fail to devote sufficient time and resources to our drug development programs or if their performance is substandard, it will delay, and potentially materially adversely affect, the development and commercialization of our products. Moreover, these parties also may have relationships with other commercial entities, some of which may compete with us and our partners. If they assist our competitors, it could harm our competitive position.

If we or our partners lose our relationship with any one or more of these parties after development efforts are commenced, there could be a significant delay in both identifying another comparable provider and then contracting for its services. An alternative provider may not be available on reasonable terms, if at all. Even if we locate an alternative provider, it is likely that this provider may need additional time to respond to our needs and may not provide the same type or level of service as the original provider. In addition, any alternative provider will be subject to current Good Laboratory Practices (“cGLP”) and similar foreign standards and neither we nor our partners have control over compliance with these regulations by these providers. Consequently, if these providers do not adhere to these practices and standards, the development and commercialization of any products that we may seek to develop could be delayed.

We have limited manufacturing experience or resources, and, to the extent that we engage in a business that involve the manufacturing of pharmaceutical products, we will have to either incur significant costs to develop this expertise or rely on third parties to manufacture our products.

We have no manufacturing experience, and thus have depended on a limited number of third parties in connection with our historical business operations. These third parties might not be able to deliver in a timely manner, on acceptable terms, or at all. There are a limited number of manufacturers that supply the materials needed for the development of the products and product candidates related to our historical business operations. There are risks inherent in pharmaceutical manufacturing that could affect the ability of our contract manufacturers to meet our delivery requirements or provide adequate amounts of material to meet our needs. To fulfill our supply requirements, we may also need to secure alternative suppliers.

The manufacturing process for any of the pharmaceutical products that we may develop or acquire is subject to the FDA approval process, and we or our partners will need to contract with manufacturers who can meet all applicable FDA requirements on an ongoing basis. If we are unable to obtain or maintain contract manufacturing for

these product candidates or approved products, or to do so on commercially reasonable terms, we may not be able to successfully develop and commercialize any products.

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To the extent that we enter into manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner and consistent with regulatory requirements, including those related to quality control and quality assurance. The failure of a third-party manufacturer to perform its obligations as expected could adversely affect our business in a number of ways.

If a third-party manufacturer with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources or enter into an agreement with a different third-party manufacturer, which we may not be able to do on acceptable terms, if at all. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget, or to sell approved products in sufficient quantities. Furthermore, a manufacturer may possess technology related to the manufacture of our product candidates or approved products that such manufacturer owns independently. This would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our products.

Risks Related to our Intellectual Property and Other Legal Matters

If we are unable to adequately protect our proprietary technology from legal challenges, infringement or alternative technologies, our competitive position may be hurt, and our operating results may be negatively impacted.

Our business has been based upon the development, acquisition and commercialization of pharmaceutical products, and we have relied on the issuance of patents, both in the U.S. and internationally, for protection against competitive technologies. Although we believe we exercise the necessary due diligence in our patent filings, our proprietary position is not established until the appropriate regulatory authorities actually issue a patent, which may take several years from initial filing or may never occur.

Moreover, even the established patent positions of pharmaceutical and biotechnology companies are generally uncertain and involve complex legal and factual issues. Although we believe our issued patents are valid, third parties may infringe our patents or may initiate proceedings challenging the validity or enforceability of our patents. The issuance of a patent is not conclusive as to its claim scope, validity or enforceability. Challenges raised in patent infringement litigation we initiate or in proceedings initiated by third parties may result in determinations that our patents have not been infringed or that they are invalid, unenforceable or otherwise subject to limitations. In the event of any such determinations, third parties may be able to use the discoveries or technologies claimed in our patents without paying us licensing fees or royalties, which could significantly diminish the value of these discoveries or technologies. As a result of such determinations, we may be enjoined from pursuing research, development and/or commercialization of products or may be required to obtain licenses, if available, to the third-party patents or to develop or obtain alternative technology. Responding to challenges initiated by third parties may require significant expenditures and divert the attention of our management and key personnel from other business concerns.

Furthermore, it is possible that others will infringe or otherwise circumvent our issued patents and that we will be unable to fund the cost of litigation against them or that we would elect not to pursue litigation. In addition, enforcing our patents against third parties may require significant expenditures regardless of the outcome of such efforts. We also cannot assure you that others have not filed patent applications for technology covered by our pending applications or that we were the first to invent the technology. There may also exist third party patents or patent applications relevant to our products that may block or compete with the technologies covered by our patent applications and third parties may independently develop IP similar to our patented IP, which could result in, among other things, interference proceedings in the U.S. Patent and Trademark Office to determine priority of invention.

In addition, we may not be able to protect our established and pending patent positions from competitive technologies, which may provide more effective therapeutic benefit to patients and which may therefore make our products, technology and proprietary position obsolete.

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We also rely on copyright and trademark protection, trade secrets, know-how, continuing technological innovation and licensing opportunities. In an effort to maintain the confidentiality and ownership of our trade secrets and proprietary information, we have typically required our employees, consultants, advisors and others to whom we disclose confidential information to execute confidentiality and proprietary information agreements. However, it is possible that these agreements may be breached, invalidated or rendered unenforceable, and if so, there may not be an adequate corrective remedy available. Furthermore, we may from time to time hire personnel formerly employed by other companies involved in one or more areas similar to the activities we conduct. In some situations, our confidentiality and proprietary information agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants or advisors have prior employment or consulting relationships. Although we have typically required our employees and consultants to maintain the confidentiality of all confidential information of previous employers, we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of their prior affiliations. Finally, others may independently develop substantially equivalent proprietary information and techniques, or otherwise gain access to our trade secrets. Our failure to protect our proprietary information and techniques may inhibit or limit our ability to exclude certain competitors from the applicable market and execute our business strategies.

Our inability to adequately protect our proprietary intellectual property from legal challenges, infringement or alternative technologies could adversely impact our competitive position, and which would negatively impact our future results and prospects.

Because intellectual property rights are of limited duration, expiration of intellectual property rights and licenses will negatively impact our operating results.

Intellectual property rights, such as patents and license agreements based on those patents, generally are of limited duration. Therefore, the expiration or other loss of rights associated with IP and IP licenses, including as a result of the failure to pay any fees and expenses required to maintain such IP and IP licenses, can negatively impact our business, and the future sales of our products. Due to our recent financial condition, we have been unable to keep current on the maintenance fees for all of our existing IP.

Our patent applications may be inadequate in terms of priority, scope or commercial value.

We apply for patents covering our discoveries and technologies as we deem appropriate and as our resources permit. However, we or our partners or licensors may fail to apply for patents on important discoveries or technologies in a timely fashion or at all. Also, our pending patent applications may not result in the issuance of any patents. These applications may not be sufficient to meet the statutory requirements for patentability, and therefore we may be unable to obtain enforceable patents covering the related discoveries, technologies, or products we may want to commercialize. In addition, because patent applications are maintained in secrecy for approximately 18 months after filing, other parties may have filed patent applications relating to inventions before our applications covering the same or similar inventions. In addition, foreign patent applications are often published initially in local languages, and until an English language translation is available it can be impossible to determine the significance of a third-party invention. Any patent applications filed by third parties may prevail over our patent applications or may result in patents that issue alongside patents issued to us, leading to uncertainty over the scope of the patents or the freedom to practice the claimed inventions.

Although we have acquired and in-licensed a number of issued patents, the discoveries, technologies or products covered by these patents may have limited therapeutic or commercial value. Also, issued patents may not provide commercially meaningful protection against competitors. Other parties may be able to design around our

issued patents or independently develop products having effects similar or identical to our patented product candidates or approved products. In addition, the scope of our patents is subject to considerable uncertainty and competitors or other parties may obtain similar patents of uncertain scope.

We have depended in the past with respect to our prior business operations, and we may depend in the future, on technologies we license, and if we lose the right to license such technologies or we fail to license new technologies in the future, our ability to develop or commercialize new or existing products would be harmed.

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We have depended in the past with respect to our prior business operations, and we may depend in the future, on licenses from third parties for certain of our technologies, products and product candidates. If our license with respect to any of these technologies or products is terminated for any reason, the development and/or commercialization of the products contemplated by the licenses would be delayed, or suspended altogether, while we seek to license similar products or technology (which licenses may not be available on terms acceptable to us or at all) or develop new non-infringing products or technology.

We may be required to defend lawsuits or pay damages for product liability claims.

Our business related to the prior commercialization of Prestalia exposed us to potential product liability risks that are inherent in the development and marketing of pharmaceutical products. The risk exists even with respect to those drugs that are approved by regulatory agencies for commercial distribution and sale and are manufactured in facilities licensed and regulated by regulatory agencies. Product liability claims could result in an FDA investigation of the safety and effectiveness of our products, the manufacturing processes and facilities with respect to our products, and our marketing programs, and potentially a recall of our products or more serious enforcement action, or suspension or withdrawal of approvals. Any product liability claims, regardless of their merits, and regardless of whether we are still commercializing the applicable product, could be costly, divert management's attention, delay or prevent completion of our development and commercialization programs, and adversely affect our reputation, the demand for our products and our stock price. We currently have no product liability insurance which we believe is appropriate for our stage of development, including our prior efforts relating to the marketing and sale of Prestalia. Any product liability insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have a material adverse effect on our business.

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Risks Related to our Industry

To the extent that we continue to operate in the biopharmaceutical industry, if we or any of our partners, consultants, collaborators, manufacturers, vendors or service providers fail to comply with healthcare laws and regulations, or legal obligations related to privacy, data protection and information security, we or they could be subject to enforcement actions, which could result in penalties and negatively affect our ability to develop, market and sell our products.

If the operations in which we may engage are found to be in violation of any such health care laws and regulations, we may be subject to penalties, including administrative, civil and criminal penalties, monetary damages, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA or foreign regulatory authorities, or exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, any of which could adversely affect our financial results. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is

successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

If we fail to comply with the laws or regulations that may be applicable to us, we could be subject to enforcement actions, which could affect our ability to successfully develop and commercialize the products and product candidates that we may develop or acquire and could harm our reputation and lead to reduced acceptance of our products.

Any drugs that we may commercialize in the future may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which, once such drugs are commercialized, could have a material adverse effect on our business and financial results.

To the extent that we continue to engage in the biopharmaceutical industry, our ability to commercialize any products successfully will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other third-party payors. In many jurisdictions, a product must be approved for reimbursement before it can be approved for sale in that jurisdiction. Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of the products that we may develop and/or acquire.

It is possible that any products that we bring to the market in the future may not be considered cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell such products on a competitive basis, or at a price that allows us to be profitable. Increasingly, the third-party payors, such as government and private insurance plans, who reimburse patients or healthcare providers, are requiring that drug companies provide them with predetermined discounts from list prices and are seeking to reduce the prices charged or the amounts reimbursed for pharmaceutical products. If the coverage provided for any products we develop, acquire or commercialize is inadequate in light of our development, sales and other costs, our return on investment could be adversely affected.

There may be significant delays in obtaining coverage for newly-approved products, and coverage may be more limited than the purposes for which the drug is approved by the FDA or foreign regulatory authorities. Moreover, eligibility for coverage does not imply that any drug will be reimbursed in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent.

Reimbursement may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates. However, no uniform policy requirement for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for products that we may seek to commercialize could have a material adverse effect on our operating results and our financial condition.

We believe that the efforts of governments and third-party payors to contain or reduce the cost of healthcare and legislative and regulatory proposals to broaden the availability of healthcare will continue to affect the business and financial condition of pharmaceutical companies. Specifically, there have been several recent U.S. Congressional

inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. A number of other legislative and regulatory changes in the healthcare system in the United States have been proposed or enacted in recent months and years, and such efforts have expanded substantially in recent years. These developments have included prescription drug benefit legislation that was enacted and took effect in January 2006, healthcare reform legislation subsequently enacted by certain states, and major healthcare reform legislation that was passed by Congress and enacted into law in the United States in 2010. Future developments could, directly or indirectly, affect our ability to sell any products that we may develop and/or acquire at a favorable price.

For example, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act (ACA), contains provisions that affect companies in the pharmaceutical industry and other healthcare related industries by imposing additional costs and changes to business practices. The financial impact of the U.S. healthcare reform legislation over the next few years will depend on a number of factors, including, without limitation, the policies reflected in implementing regulations and guidance, and changes in sales volumes for products affected by the new system of rebates, discounts and fees.

Members of Congress and the current presidential administration have expressed an intent to pass legislation or adopt executive orders to fundamentally change or repeal parts of the ACA. While Congress has not passed repeal legislation to date, several actions have been taken that revise and/or impact the ACA, including, without limitation, the Bipartisan Budget Act of 2018 that, among other things, amended the ACA to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole.” Congress may consider other legislation to replace elements of the ACA. The implications of the ACA, its possible repeal, any legislation that may be proposed to replace the ACA, or the political uncertainty surrounding any repeal or replacement legislation for our future business and financial condition, if any, are not yet clear.

The costs of prescription pharmaceuticals in the U.S. recently has also been the subject of considerable discussion in the U.S., and members of Congress and the current presidential administration have stated that they will address such costs through new legislative and administrative measures. To date, there have been several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, Congress and the current presidential administration have each indicated that it will continue to pursue new legislative and/or administrative measures to control drug costs.

Individual state legislatures have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing. Some of these measures include price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for any products we may develop and/or acquire, once approved, or put pressure on the pricing of such products.

The biopharmaceutical market is intensely competitive. If we are unable to compete effectively with existing drugs and commercialization platforms, and existing and new treatment methods and technologies, we may be unable to commercialize successfully any drugs that we develop or acquire.

The biopharmaceutical market is intensely competitive and rapidly changing. Many large and small pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are pursuing the development of drugs or treatments for the same diseases and conditions that we may target. We anticipate that many of our competitors will have:

- much greater financial, technical and human resources than we have at every stage of the discovery, development, manufacture, acquisition and commercialization of products;

- more extensive experience in pre-clinical testing, conducting clinical trials, obtaining regulatory approvals, and in manufacturing, marketing and selling pharmaceutical products;

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- additional products that have been approved or are in late stages of development; and
- collaborative arrangements in our target markets with leading companies and research institutions.

The products that we may develop and/or acquire may face intense competition from drugs or treatments that have already been approved and accepted by the medical community for the treatment of the conditions for which we may develop or commercialize drugs or treatments, or from new drugs or technologies that enter the market. It is possible that a significant number of drugs will be under development, and may become commercially available in the future, for the treatment of the conditions for which we may try to develop or commercialize drugs. These drugs may be more effective, safer, less expensive, or marketed and sold more effectively, than any products we and our partners develop or commercialize.

Our competitors may develop or commercialize products or treatments with significant advantages over any products we develop, acquire or commercialize. Our competitors may therefore be more successful in commercializing their products than we are, which could adversely affect our competitive position and business. Competitive products or treatments may make any products we develop, acquire or commercialize obsolete or noncompetitive before we can recover the expenses of developing, acquiring and/or commercializing such products. Furthermore, we may also face competition from existing and new treatment methods that reduce or eliminate the need for drugs, such as the use of advanced medical devices. The development of new medical devices, technologies or other treatment methods for the conditions that we may target could make our products noncompetitive, obsolete or uneconomical.

Risks Related to our Common Stock

The trading price of our common stock has been volatile, and investors in our common stock may experience substantial losses.

The trading price of our common stock has been volatile and may become volatile again in the future. The trading price of our common stock could decline or fluctuate in response to a variety of factors, including:

- our general financial condition and ability to maintain sufficient capital to continue operations;
- the progress and outcome of our efforts to restructure and revitalize our business operations;
- our ability to enter into and maintain collaborative arrangements with third parties;
- our ability to meet the performance estimates of securities analysts;
- changes in buy/sell recommendations by securities analysts;
- negative results relating to our products and services;
- fluctuations in our periodic operating results;
- reverse splits or increases in authorized shares;

- substantial sales of our equity securities;
- general stock market conditions; or
- other economic or external factors.

The stock markets in general, and the markets for the securities of companies of our size and in our stage of development, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock.

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We may not be able to achieve secondary trading of our stock in certain states because our common stock is not nationally traded.

Because our common stock is not listed for trading on a national securities exchange, our common stock is subject to the securities laws of the various states and jurisdictions of the U.S. in addition to federal securities law. This regulation covers any primary offering we might attempt and all secondary trading by our stockholders. If we fail to take appropriate steps to register our common stock or qualify for exemptions for our common stock in certain states or jurisdictions of the U.S., the investors in those jurisdictions where we have not taken such steps may not be allowed to purchase our stock or those who presently hold our stock may not be able to resell their shares without substantial effort and expense. These restrictions and potential costs could be significant burdens on our stockholders.

Our common stock is quoted on the OTC Pink Sheets, which may limit the ability of our stockholders to sell their securities and may cause volatility in the price of our common stock.

Our common stock is currently quoted on the OTC Pink Sheets. Securities quoted on the OTC Pink Sheets often experience a lack of liquidity as compared to securities trading on a national securities exchange. Such securities also have experienced extreme price and volume fluctuations in recent years, which have particularly affected the market prices of many smaller companies like ours. We anticipate that our common stock will be subject to the lack of liquidity and this volume and price volatility that is characteristic of the OTC Pink Sheets.

Our common stock is considered a “penny stock,” and thereby is subject to additional sale and trading regulations that may make it more difficult to sell.

Our common stock is considered to be a “penny stock” since it does not qualify for one of the exemptions from the definition of “penny stock” under Section 3a51-1 of the Exchange Act. The principal result or effect of being designated a “penny stock” is that securities broker-dealers participating in sales of our common stock are subject to the “penny stock” regulations set forth in Rules 15c-2 through 15c-9 promulgated under the Exchange Act. For example, Rule 15c-2 requires broker-dealers dealing in penny stocks to provide potential investors with a document disclosing the risks of penny stocks and to obtain a manually signed and dated written receipt of the document at least two business days before effecting any transaction in a penny stock for the investor’s account.

Moreover, Rule 15c-9 requires broker-dealers in penny stocks to approve the account of any investor for transactions in such stocks before selling any penny stock to that investor. This procedure requires the broker-dealer to (i) obtain from the investor information concerning his or her financial situation, investment experience and investment objectives; (ii) reasonably determine, based on that information, that transactions in penny stocks are suitable for the investor and that the investor has sufficient knowledge and experience as to be reasonably capable of evaluating the risks of penny stock transactions; (iii) provide the investor with a written statement setting forth the basis on which the broker-dealer made the determination in (ii) above; and (iv) receive a signed and dated copy of such statement from the investor, confirming that it accurately reflects the investor’s financial situation, investment experience and investment objectives. Compliance with these requirements may make it more difficult and time consuming for holders of our common stock to resell their shares to third parties or to otherwise dispose of them in the market or otherwise.

Various restrictions in our charter documents and Delaware law could prevent or delay a change in control of our company that is not supported by our board of directors.

We are subject to a number of provisions in our charter documents and Delaware law that may discourage, delay or prevent a merger, acquisition or change of control that a stockholder may consider favorable. These anti-takeover provisions include:

- advance notice procedures for nominations of candidates for election as directors and for stockholder proposals to be considered at stockholders' meetings; and
- the Delaware anti-takeover statute contained in Section 203 of the Delaware General Corporation Law.

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Section 203 of the Delaware General Corporation Law prohibits a merger, consolidation, asset sale or other similar business combination between us and any stockholder of 15% or more of our voting stock for a period of three years after the stockholder acquires 15% or more of our voting stock, unless (1) the transaction is approved by our board of directors before the stockholder acquires 15% or more of our voting stock, (2) upon completing the transaction the stockholder owns at least 85% of our voting stock outstanding at the commencement of the transaction, or (3) the transaction is approved by our board of directors and the holders of 66 2/3% of our voting stock, excluding shares of our voting stock owned by the stockholder.

We have never paid dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future.

We have not paid any dividends on our common stock and do not expect to do so in the foreseeable future. In addition, the terms of any financing arrangements that we have entered into, or that we may enter into, may restrict our ability to pay any dividends. Notwithstanding the foregoing, we are required to pay and/or accrue dividends on our Series E and Series F convertible preferred stock.

A significant number of shares of our common stock are subject to options, warrants and conversion rights. The issuance of these shares, which in some cases may occur on a cashless basis, will dilute the interests of other security holders and may depress the price of our common stock.

At December 31, 2020, there were outstanding warrants to purchase up to approximately 78.2 million shares of our common stock. If any of these warrants are exercised on a cashless basis, we will not receive any cash as a result of such exercises. At December 31, 2020, there were also outstanding 100 shares of Series C Preferred Stock, which shares are convertible into 66,667 shares of common stock at an assumed conversion price of \$7.50 per share of common stock, 40 shares of Series D Stock, which shares are convertible into 50,000 shares of common stock at an assumed conversion price of \$4.00 per share of common stock, 3,458 shares of Series E Stock, which shares are convertible into approximately 34.6 million shares of common stock at an assumed conversion price of \$0.50 per share of common stock (without giving effect to any dividends on such shares of preferred stock that would increase the stated value of such shares) and 361 shares of Series F Stock, which shares are convertible into approximately 3.6 million shares of common stock at an assumed conversion price of \$0.50 per share of common stock (without giving effect to any dividends on such shares of preferred stock that would increase the stated value of such shares). In addition, we may issue a significant number of additional shares of common stock (and securities convertible into or exercisable for common stock) from time to time to finance our operations, to fund potential acquisitions, or in connection with additional stock options or restricted stock granted to our employees, officers, directors and consultants. The issuance of common stock (or securities convertible into or exercisable for common stock), and the exercise or conversion of securities exercisable for or convertible into common stock, will have a dilutive impact on other stockholders and could have a material negative effect on the market price of our common stock.

There are outstanding a significant number of shares available for future sales under Rule 144.

Many shares of our common stock (including shares issuable upon conversion of outstanding shares of preferred stock or upon exercise of outstanding warrants) may be deemed “restricted shares” and, in the future, may be sold in compliance with Rule 144 promulgated under the Securities Act of 1933, as amended (the “Securities Act”). Any sales of such shares of our common stock under Rule 144 could have a depressive effect on the market price of our common stock. In general, under Rule 144, a person who is not deemed to have been an affiliate of ours at any time during the three months preceding a sale, and who has beneficially owned restricted securities within the meaning of Rule 144 for at least six months (including any period of consecutive ownership of preceding non-affiliated holders) would be entitled to sell those shares, subject only to the availability of current public information about us. A non-affiliated person who has beneficially owned restricted securities within the meaning of Rule 144 for at least one year would be entitled to sell those shares without regard to the provisions of Rule 144. A person who is deemed to be an affiliate of ours and who has beneficially owned restricted securities within the meaning of Rule 144 for at least six months would be entitled to sell within any three-month period a number of shares that does not exceed the greater of one percent of the then outstanding shares of our common stock or the average weekly trading volume of our common stock during the four calendar weeks preceding such sale. Such sales are also subject to certain manner of sale provisions, notice requirements and the availability of current public information about us.

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Our Board of Directors has the ability to issue “blank check” Preferred Stock.

Our Certificate of Incorporation authorizes the issuance of up to 100,000 shares of “blank check” preferred stock, with such designation rights and preferences as may be determined from time to time by our Board of Directors. Our Board is empowered, without shareholder approval, to issue shares of preferred stock with dividend, liquidation, conversion, voting or other rights which could adversely affect the voting power or other rights of the holders of our common stock. In the event of such issuances, the preferred stock could be utilized, under certain circumstances, as a method of discouraging, delaying or preventing a change in control of our company. Although we have no present intention to issue any additional shares of our preferred stock in the immediate future, there can be no assurance that we will not do so in the future.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not Applicable.

ITEM 2. PROPERTIES

We do not own or lease any real property or facilities that are material to our current business operations. If we advance our business operations, we may seek to lease additional facilities of our own in order to support our operational and administrative needs. There can be no assurance that such facilities will be available, or that they will be available on suitable terms. Our inability to obtain such facilities could have a material adverse effect on our future plans and operations.

ITEM 3. LEGAL PROCEEDINGS

Currently, there is no material litigation pending against our company. From time to time, we may become a party to litigation and subject to claims incident to the ordinary course of our business. Although the results of such litigation and claims in the ordinary course of business cannot be predicted with certainty, we believe that the final outcome of such matters will not have a material adverse effect on our business, results of operations or financial condition. Regardless of outcome, litigation can have an adverse impact on us because of defense costs, diversion of management resources and other factors.

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

Market Information

Our common stock trades on the OTC Pink Sheets under the symbol "ATRX". On March 30, 2021, the closing price of our common stock reported by the OTC Pink Sheets was \$0.09 per share.

Holders of record

As of March 31, 2021, there were approximately 51 beneficial holders of record of our common stock. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of beneficial holders represented by these record holders.

Dividends

Payment of dividends and the amount of dividends depend on matters deemed relevant by our Board, such as our results of operations, financial condition, cash requirements, future prospects and any limitations imposed by law, credit agreements and debt securities. To date, we have not paid any cash dividends or stock dividends on our common stock. We currently anticipate that we will not pay any cash dividends on our common stock in the foreseeable future. Furthermore, the terms of the financing arrangements that we have entered into any financing arrangements that we may enter into in the future, may restrict our ability to pay any dividends on our common stock.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Securities Authorized for Issuance under Equity Compensation Plans

See Part III, Item 12 "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" of this report for the information called for by this item

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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

Overview

The following Management's Discussion and Analysis of Financial Condition and Results of Operations is intended to provide information necessary to understand our audited consolidated financial statements for the two-year period ended December 31, 2020 and highlight certain other information which, in the opinion of management, will enhance a reader's understanding of our financial condition, changes in financial condition and results of operations. In particular, the discussion is intended to provide an analysis of significant trends and material changes in our financial position and the operating results of our business during the year ended December 31, 2020, as compared to the year ended December 31, 2019. This discussion should be read in conjunction with our consolidated financial statements for the two-year period ended December 31, 2020 and related notes included elsewhere in this

annual report on Form 10-K. These historical financial statements may not be indicative of our future performance. This Management's Discussion and Analysis of Financial Condition and Results of Operations contains a number of forward-looking statements, all of which are based on our current expectations and could be affected by the uncertainties and risks described throughout this filing, particularly in "Item 1A. Risk Factors."

Corporate Overview

Nature of Business

Adhera Therapeutics, Inc. and its wholly-owned subsidiaries, MDRNA Research, Inc. ("MDRNA"), Cequent Pharmaceuticals, Inc. ("Cequent"), Atossa Healthcare, Inc. ("Atossa"), and IThenaPharma, Inc. ("IThen") (collectively "Adhera," the "Company," "we," "our," or "us"), is an emerging specialty biotech company that, to the extent that resources and opportunities become available, is strategically evaluating its focus including a return to a drug discovery and development company, and a departure from active commercialization and promotion of hypertension treatment options in the U.S. market.

During 2020, to the extent that resources have been available, we have been working with our advisors to restructure our company and to identify potential strategic transactions to enhance the value of our company as such opportunities arise, including potential transactions and capital raising initiatives involving the assets relating to our legacy RNA interference programs, as well as business combination transactions with operating companies. There can be no assurance that we will be successful at identifying any such transactions, that we will continue to have sufficient resources to actively attempt to identify such transactions, or that such transactions will be available upon terms acceptable to us or at all. If we do not complete any significant strategic transactions, or raise substantial additional capital, in the immediate future, it is likely that we will discontinue all operations and seek bankruptcy protection.

Furthermore, we were evaluating all strategic options to out-license and/or divest our existing commercial assets, including any assets that we currently hold relating to Prestalia as well as our DyrctAxxess platform, which is designed to offer enhanced efficiency, control and access to the information necessary to empower patients, physicians and manufacturers to achieve optimal care. On January 4, 2021, the Company's licensing agreement for the sale and marketing of Prestalia in the US was terminated by Servier and all potential out-licensing activities related to divesting the asset were discontinued.

Background

On November 15, 2016, Adhera entered into an Agreement and Plan of Merger with IThenaPharma, Inc., a Delaware corporation, IThena Acquisition Corporation, a Delaware corporation and a wholly-owned subsidiary of IThena ("Merger Sub"), and a representative of the stockholders of IThena (the "Merger Agreement"), pursuant to which, among other things, Merger Sub merged with and into IThena, with IThena surviving as a wholly-owned subsidiary of Adhera (such transaction, the "Merger"). As a result of the Merger, the former holders of IThena common stock immediately prior to the completion of the Merger owned approximately 65% of the issued and outstanding shares of Adhera common stock immediately following the completion of the Merger.

Adhera was incorporated under the laws of the State of Delaware under the name Nastech Pharmaceutical Company on September 23, 1983, and IThena was incorporated under the laws of the State of Delaware on September 3, 2014. IThena is deemed to be the accounting acquirer in the Merger, and thus the historical financial statements of IThena will be treated as the historical financial statements of our company and will be reflected in our quarterly and annual reports for periods ending after the effective time of the Merger. Accordingly, beginning with our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, we started to report the results of IThena and Adhera and their respective subsidiaries on a consolidated basis.

Subsequent to the Merger, we executed on our strategy to become a commercial stage pharmaceutical company by acquiring Prestalia from Symplmed Pharmaceuticals LLC in June 2017. Prestalia is an FDA-approved and marketed anti-hypertensive drug. Prestalia is an FDC of perindopril arginine, which is an ACE inhibitor, and amlodipine besylate, which is a calcium-channel blocker and is indicated as a first line therapy for hypertension control. The acquisition of Prestalia transitioned our company from a clinical stage company to a commercial organization. We re-introduced Prestalia into the U.S. market in June 2018, with continued promotion through December 2019, at which time we terminated our business operations, including the commercialization of Prestalia.

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Results of Operations

Comparison of the Year Ended December 31, 2020 to the Year Ended December 31, 2019

Net Sales

Net sales was approximately \$252,000 for the year ended December 31, 2019 and represented revenues from the sale of Prestalia®, net of discounts. No net sales were recorded for the year ended December 31, 2020 due to the termination of our commercial operations related to the sale of Prestalia® in December 2019.

Cost of Sales

Cost of sales was approximately \$409,000 for the year ended December 31, 2019 and represented cost of sales from the sale of Prestalia®. No cost of sales was recorded for the year ended December 31, 2020 due to the termination of our commercial operations related to the sale of Prestalia® in December 2019.

Operating Expenses

Operating expenses were \$2.0 million for the year ended December 31, 2020, a decrease of approximately \$9.1 million compared to the same period in 2019. The following table summarizes our operating expenses for the years ended December 31, 2020 and 2019:

	Year Ended		
	December 31, 2020	December 31, 2019	Change
<i>(in thousands)</i>			
Sales and marketing	\$ 839	\$ 5,260	\$ (4,421)
General and administrative	1,198	4,713	(3,515)
Amortization	—	70	(70)
Impairment of intangibles and other assets	—	1,116	(1,116)
Total operating expenses	<u>\$ 2,037</u>	<u>\$ 11,159</u>	<u>\$ (9,122)</u>

Sales and Marketing

Sales and marketing expenses decreased by approximately \$4.4 million, primarily due to the termination of our commercial operations related to the sale of Prestalia® in December 2019. Sales and marketing expenses for the year ended December 31, 2020 were primarily related to regulatory costs incurred for maintaining the Prestalia® NDA.

General and Administrative

General and administrative expenses decreased by approximately \$3.5 million for the year ended December 31, 2020, as compared to the year ended December 31, 2019, primarily due to the termination of our commercial operations related to the sale of Prestalia® in December 2019. General and administrative expenses for the year ended

December 31, 2020 were primarily related to personnel related expenses and other consulting fees incurred to maintain our public company regulatory obligations.

Amortization Expense

Amortization of intangible assets decreased by approximately \$70,000 for the year ended December 31, 2020 primarily due to the write-off of intangibles in 2019, as a result of our decision to divest assets that no longer align with our strategic objectives.

Goodwill and intangible assets impairment

The loss on impairment of \$1.1 million for year ended December 31, 2019, was a result of our strategic decision to discontinue the sale, marketing and commercialization of Prestalia®.

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Other Expenses

The following table summarizes other expenses for the year December 31, 2020 and 2019:

	Year Ended		
	December 31, 2020	December 31, 2019	Change Inc/(Dec)
<i>(in thousands)</i>			
Interest expense	\$ (1,336)	\$ (662)	\$ 674
Other income	45	-	(45)
Amortization of debt discount	(438)	-	438
Total other expense, net	<u>\$ (1,729)</u>	<u>\$ (662)</u>	<u>\$ 1,067</u>

Total net other expense for the year ended December 31, 2020 increased by approximately \$1.0 million compared to the year ended December 31, 2019. The increase is primarily due to accrued interest expense, amortization of debt issuance costs and debt discounts, from the issuance of promissory notes in 2020.

Liquidity & Capital Resources

Working Capital

	December 31, 2020	December 31, 2019	Change
<i>(in thousands)</i>			
Current assets	\$ 1	\$ 420	\$ (419)
Current liabilities	14,774	10,307	4,467
Working capital (deficiency)	<u>\$ (14,773)</u>	<u>\$ (9,887)</u>	<u>\$ (4,886)</u>

Negative working capital as of December 31, 2020 was approximately \$14.8 million as compared to negative working capital of approximately \$9.9 million as of December 31, 2019. As of December 31, 2020, current assets were approximately \$1,000 and related to cash and cash equivalents. As of December 31, 2019, current assets were approximately \$420,000, including approximately \$370,000 in prepaids and other assets, and \$50,000 in cash and cash equivalents.

As of December 31, 2020, current liabilities were approximately \$14.8 million an increase of approximately \$4.5 million from December 31, 2019 primarily due to an increase in accounts payable and accrued expenses and

dividends of approximately \$2.0 million, an increase of approximately \$1.0 million for issuance of notes payable net of issuance costs, and approximately \$1.5 million in accrued dividends for our Series E and F Preferred stock.

Cash Flows and Liquidity

The following table summarizes cash flows for the year ended December 31, 2020 and 2019:

	Year Ended	
	December 31, 2020	December 31, 2019
<i>(in thousands)</i>		
Net cash used in operating activities	\$ (588)	\$ (8,738)
Net cash used in investing activities	—	—
Net cash provided by financing activities	539	4,870
(Decrease)/Increase in cash	<u>\$ (49)</u>	<u>\$ (3,868)</u>

Net cash used in Operating Activities

Net cash used in operating activities was approximately \$0.6 million during the year ended December 31, 2020. This was primarily due to a net loss of approximately \$3.8 million, partially offset by changes in operating assets and liabilities and non-cash charges including approximately \$1.7 million of non-cash interest and the amortization of debt issuance and discount costs related to our 2020 term loans.

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Net cash used in operating activities was approximately \$8.7 million during the year ended December 31, 2019. This was primarily due to the net loss of approximately \$12.0 million, partially offset by changes in operating assets and liabilities and non-cash charges including approximately \$0.7 million of interest and the amortization of debt issuance costs related to our term loan.

Net cash used in Investing Activities

There was no cash used in or provided by investing activities during the years ended December 31, 2019 or 2020.

Net cash provided by Financing Activities

Net cash provided by financing activities of approximately \$539,000 during the year ended December 31, 2020 was primarily due to the issuance of approximately \$650,000 in promissory notes off set by debt issuance costs of \$114,000.

Net cash provided by financing activities of approximately \$4.9 million during the year ended December 31, 2019 was primarily due to the issuance of approximately \$5.7 million in promissory notes off set by debt issuance costs of \$0.7 million.

We will need to raise additional operating capital in calendar year 2021 in order to maintain our operations, restructure the Company and realize our business plan. Without additional sources of cash and/or the deferral, reduction, or elimination of significant planned expenditures, we may not have the cash resources to continue as a going concern thereafter.

Going Concern

The accompanying consolidated financial statements have been prepared on the basis that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of

business. At December 31, 2020, we had a significant accumulated deficit of approximately \$44.6 million and negative working capital of approximately \$14.8 million. For the year ended December 31, 2020, we had a loss from operations of approximately \$2.0 million and negative cash flows from operations. Our operating activities consume the majority of our cash resources. We have incurred recurring losses and negative cash flows from operations since inception we have funded our operating losses through the sale of common stock, preferred stock, warrants to purchase common stock, convertible notes and secured promissory notes.

In addition, to the extent that we continue our business operations, we anticipate that we will continue to have negative cash flows from operations, at least into the near future. However, we cannot be certain that we will be able to obtain such funds required for our operations at terms acceptable to us or at all. If we are unable to obtain additional financing in the future, there may be a negative impact on the financial viability of our company. We plan to increase working capital by managing our cash flows and expenses, divesting development assets and raising additional capital through private or public equity or debt financing. There can be no assurance that such financing or partnerships will be available on terms which are favorable to our company or at all. While our management believes that it has a plan to fund ongoing operations, there is no assurance that its plan will be successfully implemented. Failure to raise additional capital through one or more financings, divesting development assets or reducing discretionary spending could have a material adverse effect on our ability to achieve our intended business objectives. These factors raise substantial doubt about our ability to continue as a going concern.

Future Financing

We will require substantial additional funds on an immediate basis to continue our business operations. We have, in the past, raised additional capital to supplement our commercialization, clinical and pre-clinical development and operational expenses. We will need to raise additional funds through equity financing, debt financing, strategic alliances, or other sources, which may result in significant further dilution in the equity ownership of our shares or in further encumbrances being placed on our assets. There can be no assurance that additional financing will be available when needed or, if available, that it can be obtained on commercially reasonable terms, or that it will be sufficient for us to successfully engage in any of our planned business operations, including re-starting the drug development and discovery programs relating to our legacy RNA interference assets. If we are not able to obtain additional financing on a timely basis, or generate significant capital from the out-licensing and/or divestiture of existing assets, we will not be able to meet our other obligations as they become due and will be forced to scale down or even cease our operations altogether.

Off-Balance Sheet Arrangements

As of December 31, 2020, we did not have any significant off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of SEC Regulation S-K.

Critical Accounting Policies and Estimates

In preparing the financial statements, we make estimates and assumptions that have an impact on the assets, liabilities, revenue, and expenses reported. These estimates can also affect supplemental information disclosed by us, including information about contingencies, risk, and financial condition. We believe, given current facts and circumstances, that our estimates and assumptions are reasonable, adhere to GAAP, and are consistently applied. Inherent in the nature of an estimate or assumption is the fact that actual results may differ from the estimates, and estimates may vary as new facts and circumstances arise. Our significant accounting policies are more fully described in the notes to our financial statements included herein for the period ended December 31, 2020.

New and Recently Adopted Accounting Pronouncements

Any new and recently adopted accounting pronouncements are more fully described in Note 2 to our financial statements included herein for the year ended December 31, 2020.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information called for by Item 8 is included following the “Index to Financial Statements” on page F-1 contained in this Annual Report on Form 10-K.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures (as that term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”) that are designed to ensure that information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosures. In designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Any controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired control objectives.

Our principal executive officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based upon that evaluation and subject to the foregoing, our principal executive officer concluded that our disclosure controls and procedures were not effective due to the material weakness(es) in internal control over financial reporting described below.

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Management’s Annual Report on Internal Control Over Financial Reporting

Management of the Company and its consolidated subsidiaries is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is a process designed under the supervision of its principal executive and principal financial officer and effected by our Company’s Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of its consolidated financial statements for external reporting purposes in accordance with U.S. generally accepted accounting principles.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. In addition, 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.

Material Weakness in Internal Control over Financial Reporting

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2020 based on the framework established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management has determined that our internal control over financial reporting as of December 31, 2020 was not effective.

A material weakness, as defined in the standards established by the Sarbanes-Oxley Act of 2002 (the “Sarbanes-Oxley Act”), is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

The ineffectiveness of our internal control over financial reporting was due to the following material weaknesses, which were exacerbated following the termination of our business operations and personnel at the end of 2020:

- Inadequate segregation of duties consistent with control objectives;
- Lack of qualified accounting personnel to prepare and report financial information in accordance with GAAP; and
- Lack of documentation on policies and procedures that are critical to the accomplishment of financial reporting objectives.

Management’s Plan to Remediate the Material Weakness

Throughout 2021, management plans to implement measures designed to ensure that control deficiencies contributing to the material weakness are remediated, such that these controls are designed, implemented, and operating effectively. The remediation actions planned included:

- Identifying gaps in our skills base and the expertise of our staff required to meet the financial reporting requirements of a public company; and
- Continuing to develop policies and procedures on internal control over financial reporting and monitor the effectiveness of operations on existing controls and procedures.

We will continue to reassess our plans to remedy our internal control deficiencies in light of our personnel structure and our financial condition. We hope that such measures will lead to an improvement in the timely preparation of financial reports and strengthen our segregation of duties at our company. We are committed to developing a strong internal control environment, and we believe that the remediation efforts that we will implement will result in significant improvements in our control environment. Our management will continue to monitor and evaluate the relevance of our risk-based approach and the effectiveness of our internal controls and procedures over financial reporting on an ongoing basis and is committed to taking further action and implementing additional enhancements or improvements, as necessary and as funds allow.

Management’s report on internal control over financial reporting was not subject to attestation by the Company’s registered public accounting firm pursuant to rules of the SEC that permit a Smaller Reporting Company to provide only Management’s report in this annual report, which may increase the risk that weaknesses or deficiencies in our internal control over financial reporting go undetected.

Changes in Internal Control over Financial Reporting

Other than such changes as arose as a result of the termination of our business operations and the related personnel at the end of 2019, there have been no changes in our internal control over financial reporting (as defined

in Rule 13a-15(f) and 15d-15(f) under the Exchange Act) during the year ended December 31, 2020 that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

As of March 30, 2021, the number of members of our Board of Directors is fixed at two (2). The members of our Board of Directors as of such date are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>	<u>Director Since</u>
		Chief Executive Officer and Chairman of the	
Andrew Kucharchuk	40	Board	July 2020
Charles Rice	56	Director	July 2020

The biographies of each director below contain information regarding the person's service as a director, business experience, director positions held currently or at any time during the last five years, and information regarding involvement in certain legal or administrative proceedings, if applicable.

Andrew Kucharchuk – has served as the Chariman of our Board of Directors and Chief Executive Office since July 7, 2020. Previously he served as President and Chief Financial Officer of OncBioMune Pharmaceuticals, Inc. (“OncBioMune”) from February 2016 until June 2020, as Chief Executive Officer of OncBioMune from November 2019 until June 2020, and as Chief Financial Officer of OncBioMune from 2009 to September 2015. Mr. Kucharchuk has served as Acting Chief Financial Officer of OncBioMune from June 2020 to September 2020. He has served as a member of the Board of Directors of OncBioMune from September 2015 to March 2017 and from May 2020 to present. Mr. Kucharchuk is a graduate of Louisiana State University and Tulane University's Freeman School of Business, where he earned an MBA with a Finance Concentration.

We believe that Mr. Kucharchuk's prior executive experience in the industry in which we intend to operate, as well as his financial background, make him a valuable asset to our Board of Directors.

Charles L. Rice - has served as a member of our board of directors since July 10, 2020. He also served as a member of the board of directors of OncBioMune Pharmaceuticals, Inc. from November 2015 until June 2020. He has been president and former chief executive officer of Entergy New Orleans, Inc., an \$800 million a year electric and gas utility, since 2010. After his first legal private practice position in Louisiana with Jones, Walker, Waechter, Poitevent, Carrere & Denegre, L.L.P., Mr. Rice joined Entergy in the legal department in 2000, serving as senior counsel in the Entergy Services, Inc. litigation group and then as manager of labor relations litigation support in human resources. Mr. Rice was recruited into New Orleans city government in 2002 as the city attorney and later took the critical role of chief administrative officer for the City of New Orleans, where he managed 6,000 employees and the city's \$600 million budget. In 2005, the law firm of Barrasso, Usdin, Kupperman, Freeman & Sarver, LLC. recruited him back to private practice, where he was named partner. Returning to Entergy in 2009, Rice served as director of utility strategy where he was responsible for coordinating regulatory, legislative, and communications efforts to develop and execute strategies that advanced commercial objectives for the company's regulated service areas. He then served as director of regulatory affairs for Entergy New Orleans. Mr. Rice holds a bachelor's degree in business administration from Howard University, a juris doctorate from Loyola University's School of Law and master's degree in business administration from Tulane University. After graduating from Howard University, he was commissioned as a second lieutenant in the United States Army and served as a military intelligence officer with the 101st Airborne

Division (Air Assault) at Fort Campbell, Ky. While in the Army, he earned the Airborne Badge, Air Assault badge and was awarded the Army Commendation and the Army Achievement medals. He is a member of the Alabama and Louisiana State Bar Associations, the American Bar Association, the New Orleans Bar Association, and the National Bar Association.

We believe that Mr. Rice's prior management and governance experience makes him a valuable asset to our Board of Directors.

Executive Officers of Our Company

Biographical information concerning our Chief Executive Officer, who also serves as a member of our Board of Directors, is set forth above. No other executive officers are employed or are contracted by the Company.

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Family Relationships

There are no familial relationships between any of our executive officers and directors.

Director or Officer Involvement in Certain Legal Proceedings

Our directors and executive officers were not involved in any legal proceedings as described in Item 401(f) of Regulation S-K in the past ten years.

Audit Committee

Due to our financial and operational condition, and the size of our Board of Directors, the entire board functions as the audit committee. The Board of Directors authorized and approved the engagement of the independent registered public accounting firm, reviewed the results and scope of the audit and other services provided by the independent registered public accounting firm, reviewed our financial statements, reviewed and evaluated our internal control functions, approved or established pre-approval policies and procedures for all professional audit and permissible non-audit services provided by the independent registered public accounting firm and reviewed and approved any proposed related party transactions.

Code of Ethics

We have adopted a Code of Business Conduct and Ethics that applies to all of our employees and officers, and the members of our Board of Directors. The Code of Business Conduct and Ethics is available on our corporate website at www.adherathera.com. You can access the Code of Business Conduct and Ethics on our website by first clicking "About Adhera Therapeutics" and then "Corporate Governance." Printed copies are available upon request without charge. Any amendment to or waiver of the Code of Business Conduct and Ethics will be disclosed on our website promptly following the date of such amendment or waiver.

ITEM 11. EXECUTIVE COMPENSATION.

The following table sets forth information regarding compensation earned during 2020 and 2019 by our principal executive officers and our other most highly compensated executive officers as of the end of the 2020 fiscal year ("Named Executive Officers").

Name and Principal Position	Year	Salary	Bonus	Stock	Option	All Other	Total
		(\$)	(\$)	Awards	Awards	Compensation	(\$)
				(\$) ⁽¹⁾	(\$) ⁽¹⁾		

Andrew Kucharchuk, CEO and Chairman of the Board	2020	60,000	—	—	—	—	60,000
Nancy Phelan, former CEO and Secretary	2020	109,120	—	—	—	7,245	116,365
	2019	266,077	—	—	495,000 ⁽²⁾	28,636	789,713

- (1) Represents the aggregate grant date fair value of the award computed in accordance with the provisions of FASB ASC Topic 718.
- (2) Ms. Phelan was appointed to serve as our Chief Executive Officer and Secretary on April 4, 2019. Ms. Phelan resigned as an officer and director of the company effective June 15, 2020. Other compensation paid to Ms. Phelan in 2020 were for health care benefits totaling \$7,245. Other compensation paid to Ms. Phelan in 2019 include \$11,886 of health insurance benefits and \$16,750 for director fees paid to Ms. Phelan, which are reflected in the column “All Other Compensation” in the table above. In addition, on April 4, 2019, we granted to Ms. Phelan options to purchase up to 1,500,000 shares of common stock at an exercise price of \$0.37 per share, which are reflected in the column “Option Awards” in the table above. We determined that the conditions for payment of the 2019 Revenue Bonus and the 2019 Stock Price Bonus (each as defined in the Phelan Agreement (as defined below)) had not been satisfied, and as a result, options to purchase up to an aggregate of 500,000 shares of our common stock were forfeited to the company at the time of such determination. All remaining options were forfeited as a result of Ms. Phelan’s resignation, with all unvested options being forfeited on the date of resignation and with all vested options being forfeited on September 15, 2020.

Narrative Disclosures Regarding Compensation; Employment and Consulting Agreements

We have entered into employment agreements or offer letters with our two Named Executive Officers. The terms and conditions of each of the foregoing arrangements are summarized below.

Andrew Kucharchuk’s Consulting Agreement

In connection with Mr. Kucharchuk’s appointment as Chief Executive Officer and Chairman of the Board of Directors, we and Mr. Kucharchuk entered into a consulting agreement dated July 7, 2020 pursuant to which, among other things, we agreed to pay to Mr. Kucharchuk, as a consultant, a monthly fee of \$10,000. The Agreement shall be effective for a period of six to nine (6-9) months, commencing on the Effective Date of this Agreement (the “Initial Term”). Thereafter, the Agreement shall renew on a month-to-month basis by mutual agreement of the parties, subject to the right of Adhera Therapeutics and/or the Mr. Kucharchuk to terminate the Agreement. A copy of the agreement was filed as Exhibit 10.1 to our Current Report on Form 8-K dated July 7, 2020.

Nancy Phelan’s Employment Agreement

In connection with Ms. Phelan’s appointment as Chief Executive Officer and Secretary, we and Ms. Phelan entered into an employment agreement dated April 4, 2019 (the “Phelan Agreement”). A copy of the Phelan Agreement was filed as Exhibit 10.1 to our Current Report on Form 8-K dated April 4, 2019.

The Phelan Agreement provided for a three-year term and a base salary of \$360,000 per year, which is subject to review and adjustment by the Board from time to time. Ms. Phelan was eligible for an annual discretionary cash bonus with a target of 50% of her base salary, subject to her achievement of any applicable performance targets and goals established by the Board.

If the total amount of sales recognized by our company less the sum of any returns, rebates, chargebacks and distribution discounts (“Net Product Revenue”) for the portion of the 2019 fiscal year starting on April 4, 2019 and ending on the last day of the 2019 fiscal year (the “Prorated 2019 Fiscal Year”) equals or exceeds \$1.2 million, as determined by our auditors, then we shall pay to Ms. Phelan a bonus (the “2019 Revenue Bonus”) equal to \$100,000

multiplied by a fraction, the numerator of which is the number of days in the Prorated 2019 Fiscal Year during which Ms. Phelan is an employee in good standing with our company and the denominator of which is 365. Also, if the daily volume weighted average price of our common stock is not less than \$2.00 per share for a sixty (60) consecutive day period beginning on any day within the Prorated 2019 Fiscal Year, then we shall pay to Ms. Phelan a bonus (the “2019 Stock Price Bonus”) equal to \$100,000 multiplied by a fraction, the numerator of which is the number of days in the Prorated 2019 Fiscal Year during which Ms. Phelan is an employee in good standing with our company and the denominator of which is 365. Since the conditions for payment of either the 2019 Revenue Bonus or the 2019 Stock Price Bonus have not been satisfied, we are not obligated to make such payments to Ms. Phelan.

Pursuant to the Phelan Agreement, we granted to Ms. Phelan options to purchase up to 1,500,000 shares of common stock at an exercise price of \$0.37 per share, which options vest as follows: (i) options to purchase up to 400,000 shares of common stock vested immediately; (ii) options to purchase up to 600,000 shares of common stock shall vest in equal monthly installments for a two (2) year period beginning on April 4, 2020; (iii) options to purchase up to 250,000 shares of common stock shall vest on the date that we determine that Ms. Phelan has earned the 2019 Revenue Bonus; and (iv) options to purchase up to 250,000 shares of common stock shall vest on the date that we determine that Ms. Phelan has earned the 2019 Stock Price Bonus. Since the conditions for payment of the 2019 Revenue Bonus and the 2019 Stock Price Bonus have not been satisfied, the options described in clauses (iii) and (iv) of the immediately preceding sentence have not vested and have been forfeited to our company. All vested options were forfeited by Ms. Phelan on September 15, 2020 following her resignation.

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Ms. Phelan was eligible to participate in our other employee benefit plans as in effect from time to time on the same basis as are generally made available to other senior executives of our company.

If Ms. Phelan’s employment was terminated by us without “Cause” or by Ms. Phelan for “Good Reason” (each as defined in the Phelan Agreement), in each case subject to Ms. Phelan entering into and not revoking a separation agreement in a form acceptable to us, Ms. Phelan would be eligible to receive:

- accrued benefits under the Phelan Agreement through the termination date, including base salary and unreimbursed business expenses;
- severance payments equal to her then-current base salary for the Severance Period (i.e., a period equal to (i) twelve (12) months or (ii) in the event we terminate Ms. Phelan’s employment for any reason other than Cause within six (6) months following a Change of Control (as defined in the Phelan Agreement), eighteen (18) months);
- vesting of all options granted to Ms. Phelan under the Phelan Agreement that would have vested during the Severance Period had she remained employed with our company through the end of the Severance Period; and
- if Ms. Phelan timely elects and remains eligible for continued coverage under COBRA, the COBRA premiums necessary to continue the health insurance coverage in effect for Ms. Phelan and her covered dependents prior to the date of termination, until the end of the Severance Period.

If Ms. Phelan’s employment was terminated by us for Cause, by Ms. Phelan other than for Good Reason, or as a result of Ms. Phelan’s death or permanent disability, Ms. Phelan (or her estate, if applicable) would have been entitled to receive accrued benefits under the Phelan Agreement through the termination date, including base salary and unreimbursed business expenses.

Subject to her termination, Ms. Phelan is subject to a confidentiality covenant, a 12-month non-competition covenant and a 24-month non-solicitation covenant.

2020 Outstanding Equity Awards at Fiscal Year-end Table

There were no outstanding equity awards held by our Named Executive Officers as of the end of our 2020 fiscal year.

Option Re-pricings

We did not engage in any option re-pricings or other modifications to any of our outstanding equity awards to our Named Executive Officers during fiscal year 2020.

Compensation of Directors

2020 Director Compensation Table

The following Director Compensation Table sets forth information concerning compensation for services rendered by our independent directors for fiscal year 2020. However, for information about the compensation paid to those of our directors who are also Named Executive Officers (i.e., Mr. Kucharchuk and Ms. Phelan), see the Summary Compensation Table above.

Name	Fees Earned or Paid in Cash (\$)	Stock Awards (\$)	Option Awards \$(⁽¹⁾)	All Other Compensation (\$)	Total (\$)
Charles Rice	12,000	—	—	—	12,000
Uli Hacksell ⁽¹⁾	75,000	—	—	—	75,000
Timothy Boris ⁽²⁾	23,286	—	—	—	23,286
Total:	110,286	—	\$ —	\$ —	\$ 110,286

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(1) Dr. Hacksell's tenure as a director of our company ended on July 10, 2020. Dr. Hacksell was appointed to serve as a member of the Board, and as the Chairman of the Board, effective July 1, 2018. We agreed to pay to Dr. Hacksell in his capacity as Chairman of the Board, base compensation in the amount of \$150,000 per year.

(2) Timothy Boris's tenure with our company ended on June 11, 2020.

Director Compensation Program

Our compensation program for directors for the first half of 2020 consisted of an annual cash payment of \$45,000 per year, payable quarterly. In addition, we agreed to pay to: (A) the Chair of the Audit Committee an annual amount of \$15,000; (B) the Chair of the Compensation Committee an annual amount of \$7,000; (C) each member of the Audit Committee (other than the Chair) an annual amount equal to \$7,000; and (D) each member of the Compensation Committee (other than the Chair) an annual amount equal to \$3,000, in each case to be paid quarterly in advance. Further, as noted in Note 1 to the Director Compensation Table above, we agreed to pay to Dr. Hacksell in his capacity as Chairman of the Board base compensation in the amount of \$150,000 per year. In July of 2020, we agreed to pay each director an annual cash payment of \$24,000 per year, payable quarterly.

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

The following table sets forth certain information regarding the ownership of our common stock as of March 31, 2020 (the "Determination Date") by: (i) each current director of our company; (ii) each of our Named Executive

Officers; (iii) all current executive officers and directors of our company as a group; and (iv) all those known by us to be beneficial owners of more than five percent (5%) of our common stock.

Beneficial ownership and percentage ownership are determined in accordance with the rules of the SEC. Under these rules, beneficial ownership generally includes any shares as to which the individual or entity has sole or shared voting power or investment power and includes any shares that an individual or entity has the right to acquire beneficial ownership of within 60 days of the Determination Date, through the exercise of any option, warrant or similar right (such instruments being deemed to be “presently exercisable”). In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of our common stock that could be issued upon the exercise of presently exercisable options and warrants are considered to be outstanding. These shares, however, are not considered outstanding as of the Determination Date when computing the percentage ownership of each other person.

To our knowledge, except as indicated in the footnotes to the following table, and subject to state community property laws where applicable, all beneficial owners named in the following table have sole voting and investment power with respect to all shares shown as beneficially owned by them. Percentage of ownership is based on 11,112,708 shares of common stock outstanding as of the Determination Date. Unless otherwise indicated, the business address of each person in the table below is c/o Adhera Therapeutics, Inc., 8000 Innovation Parkway, Baton Rouge, LA 70820. No shares identified below are subject to a pledge.

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Name	Number of Shares	Percent of Shares Outstanding (%)
Officers and Directors:		
Andrew Kucharchuk	-	-
Charles Rice	-	-
Five Percent (5%) Holders:		
Vuong Trieu, Ph.D.	10,096,289 ⁽¹⁾	55.2%

* Beneficial ownership of less than 1.0% is omitted.

- (1) Dr. Trieu previously served as an executive officer and as a director of our company. Includes presently exercisable warrants to purchase 1,135,425 shares of common stock held by Dr. Trieu and 1,513,900 shares of common stock issuable upon the conversion of 151.39 shares of Series E Preferred Stock held by Dr. Trieu (prior to giving effect to any accrued and unpaid dividends on such shares of Series E Preferred Stock). Also includes 2,312,356 shares held by Autotelic LLC, of which entity Dr. Trieu serves as an executive officer, and 86,207 shares held by LipoMedics Inc., of which entity Dr. Trieu serves as Chairman of the Board and as an executive officer. Also includes the following shares held by Autotelic Inc., of which entity Dr. Trieu serves as Chairman of the Board: (i) 525,536 shares of common stock; (ii) presently exercisable warrants to purchase 2,706,965 shares of common stock; and (iii) 1,815,900 shares of common stock issuable upon the conversion of 181.59 shares of Series E Preferred Stock (prior to giving effect to any accrued and unpaid dividends on such shares of Series E Preferred Stock). Information based on a Schedule 13D/A filed with the SEC on April 27, 2018.

Equity Compensation Plan Information

The following table provides aggregate information as of the end of the 2020 fiscal year with respect to all of the compensation plans under which our common stock is authorized for issuance, including our 2014 Long-Term Incentive Plan and our 2018 Long-Term Incentive Plan:

	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted- Average Exercise Price of Outstanding Options, Warrants, and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column(a)) (c)
Equity compensation plans approved by security holders ⁽¹⁾	11,350	\$ 1.79	8,918,650
Equity compensation plans not approved by security holders	380,000	\$ 0.98	-
Total	391,350	\$ 1.00	8,918,650

- (1) Consists of: (i) 11,350 shares of common stock underlying awards made pursuant to our 2014 Stock Incentive Plan and (ii) no shares of common stock underlying awards made pursuant to our 2018 Long-Term Incentive Plan.

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

Approval for Related Party Transactions

It is our practice and policy to comply with all applicable laws, rules and regulations regarding related-person transactions. Our Code of Business Conduct and Ethics requires that all employees, including officers and directors, disclose to the CEO the nature of any company business that is conducted with any related party of such employee, officer or director (including any immediate family member of such employee, officer or director, and any entity owned or controlled by such persons). If the transaction involves an officer or director of our company, the CEO must bring the transaction to the attention of the Audit Committee or, in the absence of an Audit Committee the full Board, which must review and approve the transaction in writing in advance. In reviewing such transactions, the Audit Committee (or the full Board, as applicable) considers the relevant available facts and circumstances.

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Related Party Transactions

Transactions with BioMauris, LLC / Erik Emerson

During the year ended December 31, 2019 the company paid a total of approximately \$32,000 for services provided by BioMauris, LLC, of which Erik Emerson, our former Chief Commercial Officer and former director of Adhera, is Executive Chairman.

In July 2019, Mr. Emerson, became the owner of an equity interest of approximately 22% in Pharma Hub Network, our third-party network manager. During the third quarter of 2019, we terminated the relationship with Pharma Hub Network. For the year ended December 30, 2019, we recorded approximately \$62,000 of related party expense for services provided by Pharma Hub Network.

Independence of the Board of Directors

The Board of Directors utilizes NASDAQ's standards for determining the independence of its members. In applying these standards, the Board considers commercial, industrial, banking, consulting, legal, accounting, charitable and familial relationships, among others, in assessing the independence of directors, and must disclose any basis for determining that a relationship is not material. The Board has determined that one out of two of its current members, namely Mr. Rice, is an independent director within the meaning of the NASDAQ independence standards. In making this independence determination, the Board did not exclude from consideration as immaterial any relationship potentially compromising the independence of any of the above directors.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

On November 5, 2020, we were notified that the audit practice of Squar Milner, LLP ("Squar Milner") our independent registered public accounting firm, was combined with Baker Tilly US, LLP ("Baker Tilly") in a transaction pursuant to which Squar Milner combined its operations with Baker Tilly and certain of the professional staff and partners of Squar Milner joined Baker Tilly either as employees or partners of Baker Tilly. On November 1, 2020, Squar Milner resigned as the auditors of the Company and with the approval of the Audit Committee of the Company's Board of Directors, Baker Tilly was engaged as its independent registered public accounting firm.

The following table sets forth the fees billed to the Company for professional services rendered for the years ended December 31, 2020 and 2019:

Services	2020	2019
Audit Fees ⁽¹⁾	\$ 69,000	\$ 100,000
Audit-Related fees ⁽²⁾	—	—
Tax fees ⁽³⁾	5,750	21,040
Total fees	\$ 74,750	\$ 121,040

- (1) Audit Fees – These consisted of the aggregate fees for professional services rendered in connection with (i) the audit of our annual financial statements, (ii) the review of the financial statements included in our Quarterly Reports on Form 10-Q for the quarters ended March 31, June 30 and September 30, and (iv) services provided in connection with statutory and regulatory filings or engagements.
- (2) Audit-Related Fees – These consisted principally of the aggregate fees related to audits that are not included Audit Fees.
- (3) Tax Fees – These consist of professional services rendered by Independent Auditor in connection with tax compliance, tax planning and federal and state tax advice for the years ended December 31, 2020 and December 31, 2019.

Pre-Approval Policies and Procedures

The Audit Committee (or in the absence of an Audit Committee, the Board of Directors has the authority to appoint or replace our independent registered public accounting firm (subject, if applicable, to stockholder ratification). The Audit Committee (or in the absence of an Audit Committee, the Board of Directors) is also responsible for the compensation and oversight of the work of the independent registered public accounting firm (including resolution of disagreements between management and the independent registered public accounting firm regarding financial reporting) for the purpose of preparing or issuing an audit report or related work. The independent registered public accounting firm was engaged by, and reports directly to, the Audit Committee (or in the absence of an Audit Committee, the Board of Directors).

The Audit Committee (or the Board Directors, as applicable) pre-approves all audit services and permitted non-audit services (including the fees and terms thereof) to be performed for us by our independent registered public accounting firm, subject to the de minimis exceptions for non-audit services described in Section 10A(i)(1)(B) of the Exchange Act and Rule 2-01(c)(7)(i)(C) of Regulation S-X, provided that all such excepted services are subsequently approved prior to the completion of the audit. We have complied with the procedures set forth above, and the Audit Committee (or the Board of Directors, as applicable) has otherwise complied with the provisions of its charter.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(1) Financial Statements

Our consolidated financial statements are set forth in Part II, Item 8 of this Annual Report on Form 10-K and are incorporated herein by reference.

(2) Financial Statement Schedules

No financial statement schedules have been filed as part of this Annual Report on Form 10-K because they are not applicable or are not required or because the information is otherwise included herein.

(3) Exhibits required by Regulation S-K

Exhibit Number	Description
2.1	<u>Agreement and Plan of Merger dated as of March 31, 2010 by and among the Registrant, Cequent Pharmaceuticals, Inc., Calais Acquisition Corp. and a representative of the stockholders of Cequent Pharmaceuticals, Inc. (filed as Exhibit 2.1 to our Current Report on Form 8-K dated March 31, 2010, and incorporated herein by reference).</u>
2.2	<u>Agreement and Plan of Merger, dated as of November 15, 2016, by and among the Registrant, IThenA Acquisition Corporation, IThenA Pharma Inc. and Vuong Trieu as the representative of IThenA Pharma Inc. (filed as Exhibit 2.1 to our Current Report on Form 8-K dated November 15, 2016, and incorporated herein by reference).</u>
3.1	<u>Restated Certificate of Incorporation of the Registrant dated July 20, 2005 (filed as Exhibit 3.1 to our Current Report on Form 8-K dated July 20, 2005, incorporated herein by reference).</u>
3.2	<u>Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Registrant, dated June 10, 2008 (filed as Exhibit 3.1 to our Current Report on Form 8-K dated June 10, 2008, and incorporated herein by reference).</u>
3.3	<u>Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Registrant, dated July 21, 2010 (filed as Exhibit 3.1 to our Current Report on Form 8-K dated July 21, 2010, and incorporated herein by reference).</u>
3.4	<u>Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Registrant, dated July 21, 2010 (filed as Exhibit 3.1 to our Current Report on Form 8-K dated July 21, 2010, and incorporated herein by reference).</u>
3.5	<u>Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Registrant, dated July 18, 2011 (filed as Exhibit 3.1 to our Current Report on Form 8-K dated July 14, 2011, and incorporated herein by reference).</u>
3.6	<u>Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Registrant, dated December 22, 2011 (filed as Exhibit 3.1 to our Current Report on Form 8-K dated December 22, 2011, and incorporated herein by reference).</u>

- 3.7 [Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Registrant, dated August 1, 2017 \(filed as Exhibit 3.1 to our Current Report on Form 8-K dated August 1, 2017, and incorporated herein by reference\).](#)
- 3.8 [Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Registrant, dated October 4, 2018 \(filed as Exhibit 3.1 to our Current Report on Form 8-K dated October 4, 2018, and incorporated herein by reference\).](#)
- 3.9 [Amended and Restated Bylaws of the Registrant dated August 21, 2012 \(filed as Exhibit 3.7 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2011, incorporated herein by reference\).](#)
- 3.10 [Certificate of Designation, Rights and Preferences of Series A Junior Participating Preferred Stock dated January 17, 2007 \(filed as Exhibit 3.1 to our Current Report on Form 8-K dated January 19, 2007, incorporated herein by reference\).](#)
- 3.11 [Amended Designation, Rights, and Preferences of Series A Junior Participating Preferred Stock, dated June 10, 2008 \(filed as Exhibit 3.2 to our Current Report on Form 8-K dated June 10, 2008, and incorporated herein by reference\).](#)

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- 3.12 [Certificate of Designations or Preferences, Rights and Limitations of Series B Preferred Stock dated December 22, 2011 \(filed as Exhibit 3.1 to our Current Report on Form 8-K dated December 22, 2011, incorporated herein by reference\).](#)
- 3.13 [Certificate of Designation of Rights, Preferences and Privileges of Series C Convertible Preferred Stock \(filed as Exhibit 3.1 to our Current Report on Form 8-K dated March 7, 2014, incorporated herein by reference\).](#)
- 3.14 [Certificate of Designation of Rights, Preferences and Privileges of Series D Convertible Preferred Stock \(filed as Exhibit 3.1 to our Current Report on Form 8-K dated August 5, 2015, incorporated herein by reference\).](#)
- 3.15 [Certificate of Designation of Preferences, Rights and Limitations of the Series E Convertible Preferred Stock of the Registrant \(filed as Exhibit 3.1 to our Current Report on Form 8-K dated April 16, 2018, incorporated herein by reference\).](#)
- 3.16 [Certificate of Designation of Preferences, Rights and Limitations of the Series F Convertible Preferred Stock of the Registrant \(filed as Exhibit 3.1 to our Current Report on Form 8-K dated July 11, 2018, incorporated herein by reference\).](#)
- 4.1 [Form of Common Stock Purchase Warrant issued by the Registrant in March 2014 \(filed as Exhibit 4.1 to our Current Report on Form 8-K dated March 7, 2014, incorporated herein by reference\).](#)
- 4.2 [Form of Common Stock Purchase Warrant issued by the Registrant on August 7, 2015 \(filed as Exhibit 4.1 to our Current Report on Form 8-K dated August 5, 2015, incorporated herein by reference\).](#)
- 4.3 [Stock Option Agreement dated as of November 22, 2017 by and between the Registrant and Isaac Blech \(filed as Exhibit 4.2 to our Current Report on Form 8-K dated November 22, 2017, and incorporated herein by reference\). **](#)
- 4.4 [Form of Common Stock Purchase Warrant issued by the Registrant to the purchasers of its Series E Convertible Preferred Stock \(filed as Exhibit 4.1 to our Current Report on Form 8-K dated April 16, 2018, incorporated herein by reference\).](#)
- 4.5 [Form of Common Stock Purchase Warrant issued by the Registrant to the purchasers of its Series F Convertible Preferred Stock \(filed as Exhibit 4.1 to our Current Report on Form 8-K dated July 11, 2018, incorporated herein by reference\).](#)
- 4.6 [Form of Non-Qualified Stock Option Agreement entered into between the Registrant and each of Joseph W. Ramelli, Philip C. Ranker and Philippe P. Calais, Ph.D. \(filed as Exhibit 4.2 to the Registration Statement on Form S-8 of the Registrant filed with the SEC on May 3, 2019, incorporated herein by reference\).](#)
- 4.7 [Form of Secured Promissory Note issued by the Registrant between June 28, 2019 and August 5, 2019 \(filed as Exhibit 4.1 to our Current Report on Form 8-K dated June 28, 2019, incorporated herein by reference\).](#)

- 4.8 [Form of Convertible Promissory Note issued by the Registrant on February 5, 2020 \(filed as Exhibit 4.1 to our Current Report on Form 8-K dated February 5, 2020, incorporated herein by reference\).](#)
- 4.9 [Form of Common Stock Purchase Warrant issued by the Registrant on February 5, 2020 \(filed as Exhibit 4.2 to our Current Report on Form 8-K dated February 5, 2020, incorporated herein by reference\).](#)
- 4.10 [Form of Convertible Promissory Note issued by Adhera Therapeutics, Inc. to select accredited investors on February 5, 2020 \(filed as Exhibit 4.1 to our Current Report on Form 8-K dated February 11, 2020, incorporated herein by reference\).](#)
- 4.11 [Form of Common Stock Purchase Warrants issued by Adhera Therapeutics, Inc. to select accredited investors on February 5, 2020 \(filed as Exhibit 4.2 to our Current Report on Form 8-K dated February 11, 2020, and incorporated herein by reference\)](#)
- 4.12 [Form of Convertible Promissory Note issued by Adhera Therapeutics, Inc. to select accredited investors on June 26, 2020 \(filed as Exhibit 4.1 to our Current Report on Form 8-K dated June 30, 2020, incorporated her herein by reference\).](#)
- 4.13 [Form of Convertible Promissory Note issued by Adhera Therapeutics, Inc. to select accredited investors on October 30, 2020 \(filed as Exhibit 4.1 to our Current Report on Form 8-K dated November 5, 2020, incorporated her herein by reference\).](#)
- 4.14 [Form of Common Stock Purchase Warrants issued by Adhera Therapeutics, Inc. to select accredited investors on October 30, 2020 \(filed as Exhibit 4.2 to our Current Report on Form 8-K dated November 5, 2020, and incorporated herein by reference\)](#)
- 10.1 [License Agreement dated as of March 20, 2009 by and between Novartis Institutes for BioMedical Research, Inc. and the Registrant \(filed as Exhibit 10.3 to our Quarterly Report on Form 10-Q/A for the quarter ended March 31, 2009, and incorporated herein by reference\). \(1\)](#)

- 10.2 [Securities Purchase Agreement, dated as of March 7, 2014, between and among the Registrant and each purchaser of the Series C Convertible Preferred Stock of the Registrant identified on the signature pages thereto \(filed as Exhibit 10.1 to our Current Report on Form 8-K dated March 7, 2014, and incorporated herein by reference\).](#)
- 10.3 [2014 Long-Term Incentive Plan of the Registrant \(filed as Exhibit 10.2 to our Current Report on Form 8-K dated September 15, 2014, and incorporated herein by reference\).**](#)
- 10.4 [Securities Purchase Agreement, dated as of August 5, 2015, between and among the Registrant and each purchaser of the Series D Convertible Preferred Stock of the Registrant identified on the signature pages thereto \(filed as Exhibit 10.1 to our Current Report on Form 8-K dated August 5, 2015, and incorporated herein by reference\).](#)
- 10.5 [License Agreement dated February 6, 2017 between the Registrant and Lipomedics Inc. \(filed as Exhibit 10.5 to our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2017, and incorporated herein by reference\).^{\(1\)}](#)
- 10.6 [Form of Subscription Agreement used in connection with the offering of the Series E Convertible Preferred Stock of the Registrant \(filed as Exhibit 10.2 to our Current Report on Form 8-K dated May 17, 2018, and incorporated herein by reference\).](#)
- 10.7 [Employment Agreement, dated April 4, 2019, by and between Adhera Therapeutics, Inc. and Nancy R. Phelan \(filed as Exhibit 10.1 to our Current Report on Form 8-K dated April 4, 2019, and incorporated herein by reference\).**](#)
- 10.8 [Settlement Agreement, dated April 4, 2019, by and between Adhera Therapeutics, Inc. and Robert C. Moscato, Jr. \(filed as Exhibit 10.2 to our Current Report on Form 8-K dated April 4, 2019, and incorporated herein by reference\).**](#)
- 10.9 [Form of Subscription Agreement used in connection with the offering of the Series F Convertible Preferred Stock of the Registrant \(filed as Exhibit 10.34 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, incorporated herein by reference\).](#)
- 10.10 [2018 Long-Term Incentive Plan of the Registrant \(filed as Exhibit 10.35 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, incorporated herein by reference\).](#)
- 10.11 [Security Agreement, dated as of June 28, 2019, among the Registrant, IThena Pharma, Inc., Cequent Pharmaceuticals, Inc., MDRNA Research, Inc., the purchasers of secured promissory notes identified on](#)

- the signature pages thereto, and Jeff S. Phillips as agent (filed as Exhibit 10.1 to our Current Report on Form 8-K dated June 28, 2019, and incorporated herein by reference).
- 10.12 Form of Subscription Agreement used in connection with the offering of the secured promissory notes of the Registrant (filed as Exhibit 10.2 to our Current Report on Form 8-K dated August 5, 2019, incorporated herein by reference).
- 10.13 Employment Agreement, dated as of October 29, 2019, by and between the Registrant and Rhonda Stanley (filed as Exhibit 10.1 to our Current Report on Form 8-K dated October 29, 2019, and incorporated herein by reference). **
- 10.14 Securities Purchase Agreement dated as of February 5, 2020 between the Registrant and the purchasers identified in the signature pages thereto (filed as Exhibit 10.1 to our Current Report on Form 8-K dated February 5, 2020, incorporated herein by reference).
- 10.15 Consulting Agreement, dated July 7, 2020, by and between Adhera Therapeutics, Inc. and Andrew Kucharchuk (filed as Exhibit 10.1 to our Current Report on Form 8-K dated July 7, 2020, and incorporated herein by reference). **
- 21.1 Subsidiaries of the Registrant.⁽²⁾
- 23.1 Consent of Baker Tilly US, LLP, independent registered accounting firm⁽²⁾
- 31.1 Certification of our Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14 and 15d-14 under the Securities Exchange Act of 1934, as amended⁽²⁾
- 32.1 Certification of our 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⁽³⁾
- 101INS XBRL Instance Document⁽²⁾
- 101SCH XBRL Taxonomy Extension Schema Document⁽²⁾
- 101CAL XBRL Taxonomy Extension Calculation Linkbase Document⁽²⁾
- 101DEF XBRL Taxonomy Extension Definition Linkbase Document⁽²⁾
- 101LAB XBRL Taxonomy Extension Label Linkbase Document⁽²⁾
- 101PRE XBRL Taxonomy Extension Presentation Linkbase Document⁽²⁾

(1) Portions of this exhibit have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, amended, and the omitted material has been separately filed with the SEC.

(2) Filed herewith.

(3) Furnished herewith.

** Indicates management contract or compensatory plan or arrangement.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

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SIGNATURES

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

ADHERA THERAPEUTICS, INC.

By: /s/ Andrew Kucharchuk

Andrew Kucharchuk

Chief Executive Officer

Date: April 7, 2021

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

By: /s/ Andrew Kucharchuk
Andrew Kucharchuk
Chief Executive Officer and Chairman of the Board
(Principal Executive and Principal Financial and
Accounting Officer)

Date: April 7, 2021

By: /s/ Charles L. Rice
Charles L. Rice
Director

Date: April 7, 2021

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

ADHERA THERAPEUTICS, INC. CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2020

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Adhera Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Adhera Therapeutics, Inc. and its subsidiaries (the Company) as of December 31, 2020 and 2019, the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for the years then ended, and the related notes to the consolidated financial statements (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations and negative cash flows from operations. This raises substantial doubt about the Company's ability to continue as a going concern. In addition, with respect to the ongoing and evolving coronavirus (COVID-19) outbreak, which was designated as a pandemic by the World Health Organization on March 11, 2020, the outbreak has caused substantial disruption in international and U.S. economies and markets and if repercussions of the outbreak are prolonged, could have a significant adverse impact on the Company's business. Management's plans in regard to these matters also are described in Note 2. 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 audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

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

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current year audit of the consolidated financial statements that was communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

CONVERTIBLE DEBT AND WARRANT ACCOUNTING

Critical Audit Matter Description

As described in Note 3 to the consolidated financial statements, the Company issued a convertible note for approximately \$500k along with a warrant to purchase 1,944,250 shares, subject to adjustments of exercise price. The Company accounted for the note as a liability and the warrant as a freestanding instrument qualifying for equity classification.

We identified the convertible note and warrant as a critical audit matter. Accounting for the issuance of the convertible note and warrant was complex due to the inherent estimation uncertainty in the Company's valuation of the note and warrant. Management used a Monte Carlo simulation model to estimate the value of the note, embedded conversion feature, and warrant, before utilizing the relative fair value method to record the transaction. The inherent estimation uncertainty was primarily attributed to assumptions used in the Monte Carlo simulation, which involved a high degree of subjectivity.

How the Critical Audit Matter Was Addressed in the Audit

The primary procedures we performed to address this critical audit matter included:

- Obtaining an understanding of the Company's process to account for the issuance of convertible note and warrant.
- Reviewing convertible debt and warrant agreements
- Examining management's memo for accounting treatment and management specialist's valuation on convertible note and warrant.
- Tested the completeness and accuracy of the underlying data used in the Monte Carlo simulation model by tracing to terms contained in the note and warrant agreement and historical data.
- With the assistance of auditor's valuation specialist, evaluated the valuation methodology used by the Company and significant assumptions used in the Monte Carlo model by evaluating individual assumptions used by management and developing an independent model to assess the reasonableness of the Company's valuation.

/s/ Baker Tilly US LLP

We have served as the Company's auditor since 2015.

Los Angeles, California
April 7, 2021

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ADHERA THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(in thousands except share and per share data)

	December 31, 2020	December 31, 2019
<u>ASSETS</u>		
Current assets		
Cash	\$ 1	\$ 50
Prepaid expenses and other assets	—	370
Total current assets	1	420
Total assets	\$ 1	\$ 420
<u>LIABILITIES AND STOCKHOLDERS' DEFICIT</u>		
Current liabilities		
Accounts payable	\$ 2,257	\$ 1,403
Due to related party	4	4
Accrued expenses	2,112	1,005
Accrued dividends	4,083	2,565
Notes payable	6,318	5,330
Total current liabilities	14,774	10,307

Commitments and contingencies (Note 11)		
Stockholders' deficit		
Preferred stock, \$0.01 par value; 100,000 shares authorized	—	—
Series C convertible preferred stock, \$0.01 par value; \$5,100 liquidation preference; 1,200 shares authorized; 100 shares issued and outstanding as of December 31, 2020 and 2019.	—	—
Series D convertible preferred stock, \$0.01 par value; \$300 liquidation preference; 220 shares authorized; 40 shares issued and outstanding as of December 31, 2020 and 2019.	—	—
Series E convertible preferred stock, \$0.01 par value; \$5,000 liquidation preference; 3,500 shares authorized; 3,458 and 3,478 shares issued and outstanding as of December 31, 2020 and 2019, respectively.	—	—
Series F convertible preferred stock, \$0.01 par value; \$5,000 liquidation preference; 2,200 shares authorized; 361 shares issued and outstanding as of December 31, 2020 and 2019.	—	—
Series G convertible preferred stock, \$0.01 par value; \$5,000 liquidation preference; 6,000 shares authorized; no shares issued and outstanding as of December 31, 2020 and 2019.		—
Common stock, \$0.006 par value; 180,000,000 shares authorized, 11,112,708 and 10,869,530 shares issued and outstanding as of December 31, 2020 and 2019, respectively	67	65
Additional paid-in capital	29,772	29,375
Accumulated deficit	(44,612)	(39,327)
Total stockholders' deficit	(14,773)	(9,887)
Total liabilities and stockholders' deficit	\$ 1	\$ 420

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

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ADHERA THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands except share and per share data)

	For the Year Ended December 31,	
	2020	2019
Net sales	\$ —	\$ 252
Cost of sales	—	409
Gross loss	—	(157)
Operating expenses		
Sales and marketing	839	5,260
General and administrative	1,198	4,713
Amortization	—	70
Impairment of intangibles and other assets	—	1,116
Total operating expenses	2,037	11,159
Loss from operations	(2,037)	(11,316)
Other expense		
Interest expense, net	(1,774)	(662)
Other income	45	—
Loss before provision for income taxes	(3,766)	(11,978)

Provision for income taxes		
Net loss	(3,766)	(11,978)
Preferred Stock Dividends	(1,540)	(1,501)
Net Loss Applicable to Common Stockholders	<u>\$ (5,306)</u>	<u>\$ (13,479)</u>
Net loss per share - Common Stockholders, basic and diluted	<u>\$ (0.49)</u>	<u>\$ (1.24)</u>
Weighted average shares outstanding, basic and diluted	<u>10,876,513</u>	<u>10,840,870</u>

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

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ADHERA THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share and per share data)

	Series E Preferred Stock		Series F Preferred Stock		Common Stock		Additio nal Paid-in Capital	Additio nal Paid-in Capital - Warran ts	Accumulat ed Deficit	Total
	Numb er	Par Value	Numb er	Par Value	Number	Par Value	Capital			
Balance, January 1, 2019	3,488	\$ -	381	\$ -	10,761,684	\$ 65	\$ (5,384)	34,094	\$ (25,848)	\$ 2,927
Accrued dividend	-	-	-	-	-	-	-	-	(1,516)	(1,516)
Conversio n of Series E Preferred stock for common stock	(10)	-	-	-	107,846	-	-	-	4	4
Repurchas e of Series F Preferred stock	-	-	(20)	-	-	-	(100)	-	11	(89)
Share based compensati on	-	-	-	-	-	-	765	-	-	765
Net loss	-	-	-	-	-	-	-	-	(11,978)	(11,978)
Balance, December 31, 2019	3,478	-	361	-	10,869,530	\$ 65	\$ (4,719)	34,094	(39,327)	(9,887)
Accrued dividend	-	-	-	-	-	-	-	-	(1,540)	(1,540)
Conversio n of Series E Preferred stock for common stock	(20)	-	-	-	243,179	2	-	-	21	23

Issuance of warrants	-	-	-	-	-	-	-	294	-	294
Beneficial conversion feature-term loans	-	-	-	-	-	-	95	-	-	95
Share based compensation	-	-	-	-	-	-	8	-	-	8
										(3,76)
Net loss	-	-	-	-	-	-	-	-	(3,766)	6
Balance, December 31, 2020	3,45				11,112,7					(14,7
	8	\$	-	361	\$	-	09	\$	67	(4,616)
									34,388	\$
									(44,612)	\$
										73

The accompanying an integral part of these consolidated financial statements.

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ADHERA THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	For the Year Ended December 31,	
	2020	2019
Cash Flows Used in Operating Activities:		
Net loss	\$ (3,766)	\$ (11,978)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share based compensation	8	765
Impairment of intangibles and other assets	—	1,116
Amortization of intangibles	—	70
Amortization of debt issuance costs	400	360
Amortization of debt discount	439	
Depreciation	—	12
Non-cash interest expense	935	326
Bad debt expense	—	32
Gain on termination of lease	—	(7)
Loss on disposal of fixed assets	—	60
Write-off of obsolete of inventory	—	26
Changes in operating assets and liabilities:		
Accounts receivable	—	16
Inventory	—	(240)
Prepaid expenses and other assets	370	(239)
Accounts payable	854	1,133
Accrued expenses	172	(166)
Due to related party	—	(24)
Net Cash Used in Operating Activities	(588)	(8,738)
Cash Flows Provided by Financing Activities:		
Repurchase of Series F Preferred stock	—	(100)
Proceeds from issuance of notes payable	653	5,677
Notes payable issuance costs	(114)	(707)

Net Cash Provided by Financing Activities	539	4,870
Net decrease in cash	(49)	(3,868)
Cash – Beginning of Period	50	3,918
Cash - End of Period	\$ 1	\$ 50
Supplementary Cash Flow Information:		
Non-cash Investing and Financing Activities:		
Issuance of common stock for conversion of Series E Preferred	\$ 23	\$ 4
Issuance of warrants	294	—
Accrued dividends	1,540	1,505
Beneficial conversion feature	95	—

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

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ADHERA THERAPEUTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2020 AND 2019

NOTE 1 – ORGANIZATION AND BUSINESS OPERATIONS

Adhera Therapeutics, Inc. and its wholly-owned subsidiaries, MDRNA Research, Inc. (“MDRNA”), Cequent Pharmaceuticals, Inc. (“Cequent”), Atossa Healthcare, Inc. (“Atossa”), and IThenaPharma, Inc. (“IThena”) (collectively “Adhera,” or the “Company”), is an emerging specialty biotech company that, to the extent that resources and opportunities become available, is strategically evaluating its focus including a return to a drug discovery and development company.

Previously throughout most of 2019, the Company was a commercially focused entity that leveraged innovative distribution models and technologies to improve the quality of care for patients in the United States suffering from chronic and acute diseases with a focus on fixed dose combination therapies in hypertension. These efforts were primarily focused on Prestalia®, a single-pill FDC of perindopril arginine and amlodipine besylate, which the Company began marketing in June of 2018. Prestalia was developed in coordination with Les Laboratoires, Servier, a French pharmaceutical conglomerate, that sells the formulation outside the United States under the brand names Coveram® and/or Viacoram®. Prestalia was approved by the U.S. Food and Drug Administration (“FDA”) in January 2015 and was distributed through our patented DyrctAxxess platform.

In December 2019, the Company terminated its then-current business operations, including its commercial operations relating to the sale of Prestalia, and terminated the personnel associated with such operations, starting immediately, which such process being substantially completed on or prior to December 31, 2019. As a result, as of the date of this report, the Company is not engaged in any research, development, or commercialization activities, and is no longer generating any revenues from operations, including from the sale of Prestalia or any other product.

Since the end of 2019, to the extent that resources have been available, the Company has been working with its advisors to restructure our company and to identify potential strategic transactions to enhance the value of our company as such opportunities arise, including potential transactions and capital raising initiatives involving the assets relating to our legacy RNA interference programs, as well as business combination transactions with operating companies. There can be no assurance that the Company will be successful at identifying any such transactions, that it will continue to have sufficient resources to actively attempt to identify such transactions, or that such transactions will be available upon terms acceptable to us or at all. If the Company does not complete any significant strategic transactions, or raise substantial additional capital, in the immediate future, it is likely that the Company will discontinue all operations and seek bankruptcy protection.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”). The summary of significant accounting policies presented below is designed to assist in understanding the Company’s financial statements. Such financial statements and accompanying notes are the representations of Company’s management, who is responsible for their integrity and objectivity.

Principles of Consolidation

The consolidated financial statements include the accounts of Adhera Therapeutics, Inc. and the wholly-owned subsidiaries, IThenA, Cequent, MDRNA, and Atossa, and eliminate any inter-company balances and transactions.

Going Concern and Management’s Liquidity Plans

The accompanying consolidated financial statements have been prepared on the basis that the Company will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business. As of December 31, 2020, the Company had a significant accumulated deficit of approximately \$44.6 million and negative working capital of approximately \$14.8 million. For the year ended December 31, 2020, the Company had a loss from operations of approximately \$2.0 million and negative cash flows from operations. Our operating activities consume the majority of our cash resources. The Company has incurred recurring losses and negative cash flows from operations since inception and has funded its operating losses through the sale of common stock, preferred stock, warrants to purchase common stock, convertible notes and secured promissory notes.

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In addition, to the extent that the Company continues its business operations, the Company anticipates that it will continue to have negative cash flows from operations, at least into the near future. However, the Company cannot be certain that it will be able to obtain such funds required for our operations at terms acceptable to us or at all. General market conditions, as well as market conditions for companies in our financial and business position, as well as the ongoing issue arising from the COVID-19 epidemic, may make it difficult for us to seek financing from the capital markets, and the terms of any financing may adversely affect the holdings or the rights of our stockholders. If the Company is unable to obtain additional financing in the future, there may be a negative impact on the financial viability of the Company. The Company plans to increase working capital by managing its cash flows and expenses, divesting development assets and raising additional capital through private or public equity or debt financing. There can be no assurance that such financing or partnerships will be available on terms which are favorable to the Company or at all. While management of the Company believes that it has a plan to fund ongoing operations, there is no assurance that its plan will be successfully implemented. Failure to raise additional capital through one or more financings, divesting development assets or reducing discretionary spending could have a material adverse effect on the Company’s ability to achieve its intended business objectives. These factors raise substantial doubt about the Company’s ability to continue as a going concern. The consolidated financial statements do not contain any adjustments that might result from the resolution of any of the above uncertainties.

Use of Estimates

The preparation of the accompanying consolidated 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 revenue and expenses during the reported period. Significant areas requiring the use of management estimates include valuation allowance for accounts receivable and deferred income tax assets, legal contingencies and fair value of financial instruments. Actual results could differ materially from such estimates under different assumptions or circumstances.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less at the time of purchase to be cash equivalents. There were no cash equivalents as of December 31, 2020 and \$50,000 in cash equivalents as December 31, 2019.

The Company deposits its cash with major financial institutions and may at times exceed the federally insured limit. At December 31, 2020, the Company's cash balance did not exceed the federal insurance limit.

Fair Value of Financial Instruments

The Company considers the fair value of cash, accounts payable, due to related parties, notes payable, accounts receivable and accrued liabilities not to be materially different from their carrying value. These financial instruments have short-term maturities. The Company follows authoritative guidance with respect to fair value reporting issued by the Financial Accounting Standards Board ("FASB") for financial assets and liabilities, which defines fair value, provides guidance for measuring fair value and requires certain disclosures. The guidance does not apply to measurements related to share-based payments. The guidance discusses valuation techniques, such as the market approach (comparable market prices), the income approach (present value of future income or cash flow), and the cost approach (cost to replace the service capacity of an asset or replacement cost). The guidance establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. The following is a brief description of those three levels:

Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities.

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Level 2: Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3: Unobservable inputs in which little or no market data exists, therefore developed using estimates and assumptions developed by us, which reflect those that a market participant would use.

The Company's cash is subject to fair value measurement and is determined by Level 1 inputs. There were no liabilities measured at fair value as of December 31, 2020 or 2019.

Accounts Receivable, net

During the year ended December 31, 2019, the Company recorded approximately \$32,000 of bad debt expense as a result of the write-off of uncollectible accounts receivable related to amounts due from wholesalers and specialty pharmacy providers. No bad debt expense was incurred for the period ended December 31, 2020.

Impairment of Long-Lived Assets

The Company reviews all long-lived assets for impairment indicators throughout the year and perform detailed testing whenever impairment indicators are present. In addition, the Company perform detailed impairment testing for indefinite-lived intangible assets, at least annually, at December 31. When necessary, the Company records charges for impairments. Specifically:

- For finite-lived intangible assets, such as developed technology rights, and for other long-lived assets, the Company compares the undiscounted amount of the projected cash flows associated with the asset, or asset group, to the carrying amount. If the carrying amount is found to be greater, the Company records an impairment loss for the excess of book value over fair value. In addition, in all cases of an impairment review, the Company re-evaluates the remaining useful lives of the assets and modifies them, as appropriate; and

- For indefinite-lived intangible assets, such as acquired in-process R&D assets, each year and whenever impairment indicators are present, the Company determines the fair value of the asset and records an impairment loss for the excess of book value over fair value, if any.

The Company recognized \$0.3 million as a loss on impairment for the year ended December 31, 2019. The impairment determination was primarily a result of the decision to divest assets that no longer align with the Company's strategic objectives. No asset impairment was recognized for the year ended December 31, 2020.

Revenue Recognition

Revenue, Net

The Company records revenue recognition in accordance with ASC 606, Revenue from Contracts with Customers (ASC 606). The Company terminated all commercial operations in December 2019, therefore all revenue and cost of goods sold disclosure only apply to periods prior to the first quarter of 2020.

The Company sold its medicines primarily to wholesale distributors and specialty pharmacy providers under agreements with payment terms typically less than 90 days. These customers subsequently resold the Company's medicines to health care patients. Revenue was recognized when performance obligations under the terms of a contract with a customer are satisfied. The majority of the Company's contracts had a single performance obligation to transfer medicines. Accordingly, revenues from medicine sales were recognized when the customer obtained control of the Company's medicines, which occurred at a point in time, typically upon delivery to the customer. Revenue was measured as the amount of consideration the Company expects to receive in exchange for transferring medicines and was generally based upon a list or fixed price less allowances for medicine returns, rebates and discounts. Company recorded an estimate of unrealized revenue reductions, and the related liability, for bottles sold to pharmacies but not yet prescribed.

Medicine Sales Discounts and Allowances

The nature of the Company's contracts gave rise to variable consideration because of allowances for medicine returns, rebates and discounts. Allowances for medicine returns, rebates and discounts were recorded at the time of sale to wholesale pharmaceutical distributors and pharmacies. The Company applied significant judgments and estimates in determining some of these allowances. If actual results differ from its estimates, the Company would be required to make adjustments to these allowances in the future. The Company's adjustments to gross sales are discussed further below.

Patient Access Programs

The Company offered discounts to patients under which the patient received a discount on his or her prescription. In circumstances when a patient's prescription is rejected by a third-party payer, the Company would pay for the full cost of the prescription. The Company reimbursed pharmacies for this discount directly or through third-party vendors. The Company reduced gross sales by the amount of actual co-pay and other patient assistance in the period based on the invoices received. The Company also recorded an accrual to reduce gross sales for estimated co-pay and other patient assistance on units sold to distributors or pharmacies that have not yet been prescribed/dispensed to a patient. The Company calculated accrued co-pay and other patient assistance fee estimates using the expected value method. The estimate was based on contract prices, estimated percentages of medicine that would be prescribed to qualified patients, average assistance paid based on reporting from the third-party vendors and estimated levels of inventory in the distribution channel. Accrued co-pay and other patient assistance fees were included in "accrued expenses" on the consolidated balance sheet. Patient assistance programs include both co-pay assistance and fully bought down prescriptions.

Sales Returns

Consistent with industry practice, the Company maintained a return policy that allows customers to return medicines within a specified period prior to and subsequent to the medicine expiration date. Generally, medicines may be returned for a period beginning nine months prior to its expiration date and up to one year after its expiration date. The right of return expires on the earlier of one year after the medicine expiration date or the time that the medicine is dispensed to the patient. The majority of medicine returns result from medicine dating, which falls within the range set by the Company's policy and are settled through the issuance of a credit to the customer. The Company calculated sales returns using the expected value method. The estimate of the provision for returns was based upon industry experience. This period is known to the Company based on the shelf life of medicines at the time of shipment. The Company recorded sales returns in "accrued expenses" as a reduction of revenue.

Cost of Goods Sold

Distribution Service Fees

The Company included distribution service fees paid for inventory management services as cost of goods sold. The Company calculated accrued distribution service fee estimates using the most likely amount method. The Company accrued estimated distribution fees based on contractually determined amounts. Accrued distribution service fees were included in "accrued expenses" on the consolidated balance sheet.

Shipping Fees

The Company included fees incurred by pharmacies for shipping medicines to patients as cost of goods sold. The Company calculated accrued shipping fee estimates using the expected value method. The Company recorded accrued shipping fees in "accrued expenses" on the consolidated balance sheet.

Non-Commercial Product

The Company recorded the cost of non-commercial product distributed to patients as a cost of goods sold.

Royalties on Product Sales

The Company recorded royalty fees on the sale of commercial product as a cost of goods sold.

Convertible Debt and Warrant Accounting

Debt with warrants

In accordance with ASC Topic 470-20-25, when the Company issues debt with warrants, the Company treats the warrants as a debt discount, recorded as a contra-liability against the debt, and amortizes the balance over the life of the underlying debt as amortization of debt discount expense in the consolidated statements of operations. The offset to the contra-liability is recorded as additional paid in capital in the Company's consolidated balance sheets if the warrants are not treated as a derivative. The Company determines the value of the warrants using the Black-Scholes Option Pricing Model ("Black-Scholes") or the Monte Carlo Method based upon the underlying conversion features of the debt. If the debt is retired early, the associated debt discount is then recognized immediately as amortization of debt discount expense in the consolidated statements of operations.

Convertible debt – derivative treatment

When the Company issues debt with a conversion feature, it first assess whether the conversion feature meets the requirements to be treated as a derivative, as follows: a) one or more underlyings, typically the price of our common stock; b) one or more notional amounts or payment provisions or both, generally the number of shares upon

conversion; c) no initial net investment, which typically excludes the amount borrowed; and d) net settlement provisions, which in the case of convertible debt generally means the stock received upon conversion can be readily sold for cash. An embedded equity-linked component that meets the definition of a derivative does not have to be separated from the host instrument if the component qualifies for the scope exception for certain contracts involving an issuer's own equity. The scope exception applies if the contract is both a) indexed to its own stock; and b) classified in shareholders' equity in its statement of financial position.

Convertible debt – beneficial conversion feature

If the conversion feature is not treated as a derivative, the Company assesses whether it is a beneficial conversion feature ("BCF"). A BCF exists if the conversion price of the convertible debt instrument is less than the stock price on the commitment date. This typically occurs when the conversion price is less than the fair value of the stock on the date the instrument was issued. The value of a BCF is equal to the intrinsic value of the feature, the difference between the conversion price and the common stock into which it is convertible and is recorded as additional paid in capital and as a debt discount in the consolidated balance sheets. The Company amortizes the balance over the life of the underlying debt as amortization of debt discount expense in the consolidated statements of operations. If the debt is retired early, the associated debt discount is then recognized immediately as amortization of debt discount expense in the consolidated statements of operations.

If the conversion feature does not qualify for either the derivative treatment or as a BCF, the convertible debt is treated as traditional debt.

Recently Issued Accounting Pronouncements

Recently Adopted

In January 2017, the FASB issued Accounting Standards Update ("ASU") No. 2017-04, Intangibles-Goodwill and Other (Topic 350) ("ASU 2017-04"), which will simplify the goodwill impairment calculation by eliminating Step 2 from the current goodwill impairment test. The new standard does not change how a goodwill impairment is identified. The Company will continue to perform its quantitative goodwill impairment test by comparing the fair value of its reporting unit to its carrying amount, but if the Company is required to recognize a goodwill impairment charge, under the new standard, the amount of the charge will be calculated by subtracting the reporting unit's fair value from its carrying amount. Under the current standard, if the Company is required to recognize a goodwill impairment charge, Step 2 requires it to calculate the implied value of goodwill by assigning the fair value of a reporting unit to all of its assets and liabilities as if that reporting unit had been acquired in a business combination and the amount of the charge is calculated by subtracting the reporting unit's implied fair value of goodwill from the goodwill carrying amount. The standard was effective January 1, 2020. The adoption of ASU 2017-04 did not have a material impact on the Company's historical financial statements.

Not Yet Adopted

In August 2020, the FASB issued ASU No. 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity ("ASU 2020-06"), which will simplify the accounting for certain financial instruments with characteristics of liabilities and equity, including certain convertible instruments and contracts on an entity's own equity. Specifically, the new standard will remove the separation models required for convertible debt with cash conversion features and convertible instruments with beneficial conversion features. It will also remove certain settlement conditions that are currently required for equity contracts to qualify for the derivative scope exception and will simplify the diluted earnings per share calculation for convertible instruments. ASU 2020-06 will be effective January 1, 2022 for the Company and may be applied using a full or modified retrospective approach. Early adoption is permitted, but no earlier than January 1, 2021 for the Company. Management has evaluated the impact of adopting ASU 2020-06 and has determined such adoption will not have a material impact on the overall stockholders' equity (deficit) in the Company's consolidated financial statements.

Net Loss per Common Share

Basic net loss per common share is computed by dividing the net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per share includes the effect of common stock equivalents (stock options and warrants) when, under either the treasury or if-converted method, such inclusion in the computation would be dilutive. Net loss is adjusted for the dilutive effect of the change in fair value liability for price adjustable warrants, if applicable.

The following table presents the computation of net loss per share (in thousands, except share and per share data):

<i>(in thousands except share and per share data)</i>	December 31,	
	2020	2019
Numerator		
Net loss	\$ (3,766)	\$ (11,978)
Preferred stock dividends	(1,540)	(1,501)
Net Loss allocable to common stockholders	<u>\$ (5,306)</u>	<u>\$ (13,479)</u>
Denominator		
Weighted average common shares outstanding used to compute net loss per share, basic and diluted	10,876,513	10,840,870
Net loss per share of common stock, basic and diluted		
Net loss per share, basic and diluted	<u>\$ (0.49)</u>	<u>\$ (1.24)</u>

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The following number of shares have been excluded from diluted net (loss) since such inclusion would be anti-dilutive:

	Year Ended December 31,	
	2020	2019
Stock options outstanding	391,350	4,071,333
Convertible notes	33,658,590	—
Warrants	78,181,855	35,517,329
Series C Preferred Stock	66,667	66,667
Series D Preferred Stock	50,000	50,000
Series E Preferred Stock	42,055,232	39,508,382
Series F Preferred Stock	4,303,767	3,991,753
Total	<u>158,707,461</u>	<u>83,205,464</u>

Stock-Based Compensation

The Company applies the provisions of *ASC 718, Compensation—Stock Compensation* (“*ASC 718*”), which requires the measurement and recognition of compensation expense for all stock-based awards made to employees and non-employees, including stock options, in the statements of operations.

For stock options issued, the Company estimates the grant date fair value of each option using the Black-Scholes option pricing model. The use of the Black-Scholes option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected life of the option, risk-free interest rates and expected dividend yields of the common stock. For awards subject to service-based vesting conditions, including those with a graded vesting schedule, the Company recognizes stock-based compensation expense equal to the grant date fair value of stock options on a straight-line basis over the requisite service period, which is generally the vesting term. Forfeitures are recorded as they are incurred as opposed to being estimated at the time of grant and revised if and when a forfeiture becomes probable.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets, including tax loss and credit carry forwards, and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

The Company accounts for income taxes using the asset and liability method to compute the differences between the tax basis of assets and liabilities and the related financial amounts, using currently enacted tax rates.

NOTE 3 – INVENTORY

During 2019, inventory consisted of raw material and finished goods stated at the lower of cost or net realizable value with cost determined on a first-in, first-out basis. The Company reviewed the composition of inventory at each reporting period in order to identify obsolete, slow-moving, quantities in excess of expected demand, or otherwise non-saleable items.

During the year ended December 31, 2019, the Company recorded a related charge to cost of goods sold for obsolete inventory of \$26,000. In addition, the Company's recognized approximately \$456,000 for inventory impairment during the year ended December 31, 2019. The loss on impairment was due to the Company's strategic decision to discontinue the sale and commercialization of Prestalia. No loss on impairment was recognized for the year ended December 31, 2020.

NOTE 4 – PREPAID EXPENSES AND OTHER ASSETS

Prepaid expenses and other assets at December 31, 2019, included prepaid insurance of approximately \$275,000 and other expenses related to the Company's operations. At December 31, 2019, the Company recognized a loss on impairment of approximately \$338,000 for prepaid assets as a result of its strategic decision to discontinue the sale and commercialization of Prestalia. At December 31, 2020, no prepaids or other assets were recorded on the accompanying balance sheet.

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NOTE 5 - INTANGIBLE ASSETS

Acquisition of Prestalia & DyrctAxess

In June 2017, the Company entered into an Asset Purchase Agreement (the "Purchase Agreement") with Symplmed Pharmaceuticals LLC ("Symplmed") pursuant to which the Company purchased from Symplmed, for aggregate consideration of approximately \$620,000 (consisting of \$300,000 in cash plus the assumption of certain liabilities of Symplmed in the amount of approximately \$320,000), Symplmed's assets relating to a single-pill FDC of perindopril arginine and amlodipine besylate known as Prestalia® ("Prestalia"), that has been approved by the FDA for the treatment of hypertension. In addition, as part of the transactions contemplated by the Purchase Agreement: (i) Symplmed transferred to us following the closing date, the New Drug Applications for the approval of Prestalia as a new drug by the FDA; and (ii) Symplmed assigned to us all of its rights and obligations under that certain Amended and Restated License and Commercialization Agreement by and between Symplmed and Les Laboratoires Servier ("Servier") dated January 2012, pursuant to which Symplmed had an exclusive license from Servier to manufacture, have manufactured, develop, promote, market, distribute and sell Prestalia in the U.S. (and its territories and possessions) in consideration of regulatory and sales-based milestone payments and royalty payments based on net sales. Management has determined that this acquisition was deemed an asset purchase under FASB ASC 805.

The purchase price of \$620,000 was allocated based on a preliminary estimate of the fair value of the assets acquired and was included in intangible assets as of December 31, 2017. During the year ended December 31, 2018,

the allocation of the purchase price was finalized which resulted in \$161,000 of the price being allocated to raw materials received from Symplmed, and approximately \$459,000 being allocated to intangible assets.

In furtherance of the acquisition and commercialization of Prestalia, in July 2017 the Company acquired from Symplmed and its wholly-owned subsidiary, Symplmed Technologies, LLC, certain of the intellectual property assets related to the patented technology platform known as DyrctAxess, also known as Total Care, that offers enhanced efficiency, control and information to empower patients, physicians and manufacturers to help achieve optimal care for \$75,000 in cash.

Intangible Asset Summary

The Company recognized a loss on impairment of an intangible asset of \$322,000 for the year ended December 31, 2019. The loss on impairment for 2019 was due to the Company's strategic decision to discontinue the sale and commercialization of Prestalia. No loss on impairment was recognized for the year ended December 31, 2020.

Amortization expense was approximately \$70,000 for the year ended December 31, 2019. No amortization expense was recognized for the year ended December 31, 2020.

NOTE 6 - TERM LOANS

2019 Term Loan

On June 28, July 3, July 17, and August 5, 2019, the Company entered into term loan subscription agreements with certain accredited investors, pursuant to which the Company issued secured promissory notes (the "Notes") in the aggregate principal amount of approximately \$5.7 million. The Company paid \$707,000 in debt issuance costs which was recorded as a debt discount to be amortized as interest expense over the term of the loan using the straight-line method.

The Notes accrue interest at a rate of 12% per annum. Interest is payable quarterly with the first interest payment to be made on December 28, 2019, and each subsequent payment every three months thereafter.

The unpaid principal balance of the Notes, plus accrued and unpaid interest thereon, will mature on the earliest to occur of: (i) June 28, 2020 (subject to extension for up to (60) days based upon the mutual agreement of the Company and the holders of a majority of the unpaid principal balance of all outstanding Notes) or (ii) at any time following an Event of Default. The Notes may not be prepaid without the prior written consent of the holders of the Notes. The Notes are secured by a first lien and security interest on all the assets of the Company and certain of its wholly owned subsidiaries.

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On December 28, 2019, the Company defaulted on the initial interest payment on the loan and the interest rate per annum increased to the default rate of 15%.

The Company recognized approximately \$682,000 in interest expense related to the Notes for year the ended December 31, 2019 including \$360,000 related to the amortization of debt issuance costs. The Company recognized approximately \$1.2 million in interest expense related to the Notes for the year ended December 31, 2020 including 347,000 related to the amortization of debt issuances costs.

As of December 31, 2020, the debt discount and issuance costs for this term loan were fully amortized. The Company remains in default on the repayment of principal and interest on the notes.

2020 Term Loan

On February 5, 2020, the Company entered into a Securities Purchase Agreement with accredited investors pursuant to purchase: (i) original issue discount unsecured Convertible Promissory Notes (the “Notes”), issued at a 10% original issue discount, for a total purchase price of \$499,950, and (ii) warrants to purchase up to such number of shares of the common stock of the Company as is equal to the product obtained by multiplying 1.75 by the quotient obtained by dividing (A) the principal amount of the Notes by (B) the then applicable conversion price of the Notes.

The maturity date is the six (6) month anniversary of the original issue date, or August 5, 2020, or such earlier date as the Note is required or permitted to be repaid as provided thereunder, and to pay interest to the Holder on the aggregate unconverted and then outstanding principal amount of the Note. Interest shall accrue to the Holders on the aggregate unconverted and then outstanding principal amount of the Notes at the rate of 10% per annum, calculated on the basis of a 360-day year and shall accrue daily commencing on the original issue date until payment in full of the outstanding principal (or conversion to the extent applicable), together with all accrued and unpaid interest, liquidated damages and other amounts which may become due thereunder, has been made.

On or after May 5, 2020 until the Notes are no longer outstanding, the Notes shall be convertible, in whole or in part, at any time, and from time to time, into shares of Common Stock at the option of the noteholder. The conversion price shall be the lower of: (i) \$0.50 per share of Common Stock and (ii) 70% of the volume weighted average price of the Common Stock on the trading market on which the Common Stock is then listed or quoted for trading for the prior ten (10) trading days (as adjusted for stock splits, stock combinations and similar events); provided, that if the Notes are not prepaid on or before May 5, 2020, then the conversion price shall be the lower of (x) 60% of the conversion price as calculated above or (y) \$0.05 (as adjusted for stock splits, stock combinations and similar events). The conversion price of the Notes shall also be adjusted as a result of subsequent equity sales by the Company, with customary exceptions.

The exercise price of the Warrants shall be equal to the conversion price of the Notes, provided, that on the date that the Notes are no longer outstanding, the exercise price shall be fixed at the conversion price of the Notes on such date, with the exercise price of the Warrants thereafter (and the number of shares of Common Stock issuable upon the exercise thereof) being subject to adjustment as set forth in the Warrants. The warrants have a 5-year term.

The Company recorded a discount related to the warrants of approximately \$322,000, including a discount of \$30,000 and issuance costs of \$53,000 based on the relative fair value of the instruments as determined by using the Monte-Carlo simulation model. The Company also recorded a debt discount related to the convertible debt of approximately \$21,000 and debt issuance cost of \$38,000 using the relative fair value method to be amortized as interest expense over the term of the loan using the straight-line method.

On June 15, 2020, the Company defaulted on certain covenants in the 2020 term loan and the interest rate reset to the default rate of 18%.

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The Company recognized \$113,000 in interest expense related to the notes for the year ended December 31, 2020, including \$38,000 related to the amortization of debt issuance costs. The Company amortized \$343,000 of debt discount for the year ended December 31, 2020.

As of December 31, 2020, the debt discount and issuance costs for this term loan were fully amortized. The Company remains in default on the repayment of principal and interest on the notes.

Secured Promissory Note – June 2020

On June 26, 2020, the Company issued to an existing investor in the Company a 10% original issue discount Senior Secured Convertible Promissory Note for a purchase price of \$52,500. The Note matures on the date that is the six (6) month anniversary of the original issue date. Interest shall accrue on the aggregate unconverted and then outstanding principal amount of the Note at the rate of 10% per annum, calculated on the basis of a 360-day year. The

Company recorded approximately \$14,000 in debt issuance cost to be amortized over the life of the loan using the straight-line method.

On or after September 24, 2020, the Note shall be convertible, in whole or in part, into shares of common stock of the Company at the option of the noteholder at a conversion price of \$0.02 (as adjusted for stock splits, stock combinations and similar events); provided, that if an event of default has occurred under the Note, then the conversion price shall be 65% of the lowest closing bid price of the Company's common stock as reported on its principal trading market for the twenty consecutive trading day period ending on (and including) the trading day immediately preceding the date on which the conversion notice was delivered. The conversion price shall also be adjusted as a result of subsequent equity sales by the Company. Because the share price on the commitment date was in excess of the conversion price, the Company recorded a beneficial conversion feature of \$50,000 related to this note that was credited to additional paid in capital, and reduced the carrying amount. At the commitment date, the actual intrinsic value of the beneficial conversion feature was approximately \$203,000. The discount recorded is being amortized to interest expense over the life of the loan using the straight-line method.

The obligations of the Company under the Note are secured by a senior lien and security interest in all of the assets of the Company and certain of its wholly-owned subsidiaries pursuant to the terms and conditions of a Security Agreement dated June 26, 2020 by the Company in favor of the noteholder. In connection with the issuance of the Note, the holders of the secured promissory notes that the Company issued to select accredited investors between June 28, 2019 and August 5, 2019 in the aggregate principal amount of approximately \$5.7 million agreed to subordinate their lien and security interest in the assets of the Company and its subsidiaries as set forth in the Security Agreement dated June 28, 2019 that such holders entered into with the Company and its subsidiaries to the security interest granted to the holder of the Note.

On August 5, 2020, the Company defaulted on certain covenants in the loan and the interest rate reset to the default rate of 18%.

For the year ended December 31, 2020, the Company recognized approximately \$19,000 in interest expense including \$14,000 related to the amortization of debt issuance costs, respectively. For the year ended December 31, 2020, the Company recognized \$56,000 related to the amortization of debt discount.

As of December 31, 2020, the debt discount and issuance costs for the loan were fully amortized. The Company remains in default on the repayment of principal and interest on the notes.

Secured Promissory Note – October 2020

On October 30, 2020, the Company issued to an existing investor in and lender to the Company a 10% original issue discount senior secured convertible promissory note for a purchase price of \$100,000. Additionally, the Company issued the noteholder 1,587,301 warrants to purchase the Company's common stock at \$0.08 per share subject to certain adjustments as defined in the agreement. The Company recorded approximately \$9,000 in debt issuance cost to be amortized over the life of the loan using the straight-line method.

The note matures on April 30, 2021, or such earlier date as the note is required or permitted to be repaid. Interest shall accrue on the aggregate unconverted and then outstanding principal amount of the note at the rate of 10% per annum, calculated on the basis of a 360-day year.

The note is convertible, in whole or in part, at any time, and from time to time, into shares of the common stock of the Company at the option of the noteholder at a conversion price of \$0.07 (as adjusted for stock splits, stock combinations and similar events); provided, that if an event of default has occurred under the Note, then the conversion price shall be 70% of then conversion price. The conversion price will be adjusted as a result of subsequent equity sales by the Company. The obligations of the Company under the note are secured by a senior lien and security interest in all of the assets of the Company.

The Company recorded a discount related to the warrants of approximately \$66,000, including a discount of \$6,000 and issuance costs of \$5,000 based on the relative fair value of the instruments as determined by using the Black-Scholes valuation model. The Company recorded a beneficial conversion feature of \$45,000 related to the note that was credited to additional paid in capital, and reduced the carrying amount. The discount recorded is being amortized to interest expense over the life of the loan using the straight-line method. At the commitment date, the actual intrinsic value of the beneficial conversion feature was approximately \$69,000. The Company also recorded a debt discount related to the convertible debt of approximately \$5,000 and debt issuance cost of \$4,000 using the relative fair value method to be amortized as interest expense over the term of the loan using the straight-line method.

For the year ended December 31, 2020, the Company recognized approximately \$3,300 in interest expense including \$1,300 related to the amortization of debt issuance costs, respectively. For the year ended December 31, 2020, the Company recognized \$40,000 related to the amortization of debt discount.

NOTE 7 - RELATED PARTY TRANSACTIONS

Due to Related Party

The Company and other related entities have had a commonality of ownership and/or management control, and as a result, the reported operating results and /or financial position of the Company could significantly differ from what would have been obtained if such entities were autonomous.

In 2016, the Company entered into a Master Services Agreement (“MSA”) with Autotelic Inc., a related party that is partly-owned by one of the Company’s former Board members, namely Vuong Trieu, Ph.D. Autotelic Inc. currently owns less than 5% of the Company. The MSA stated that Autotelic Inc. would provide business functions and services to the Company and allowed Autotelic Inc. to charge the Company for these expenses paid on its behalf. The Company terminated the MSA effective October 31, 2018. Dr. Trieu resigned as a director of our company effective October 1, 2018.

In accordance with the MSA, Autotelic Inc. billed the Company for personnel and service expenses incurred on behalf of the Company. An unpaid balance of approximately \$4,000 is included in due to related party in the accompanying balance sheets as of December 31, 2020 and 2019.

Transactions with BioMauris, LLC/Erik Emerson

Eric Emerson was the former Chief Commercial Officer and former member of the Company’s Board of Directors.

Until February of 2019, the Company had engaged the services of BioMauris, LLC, of which Erik Emerson was Executive Chairman.

During the year ended December 31, 2019 the Company recorded approximately \$32,000 for related party expenses incurred under the agreement. No related party liability was recorded as of December 31, 2019 for related party expenses with BioMauris, LLC.

In July 2019, Mr. Emerson, became the owner of an equity interest of approximately 22% in Pharma Hub Network, the Company’s third-party network manager. During the third quarter of 2019, the Company terminated the relationship with Pharma Hub Network. For the year ended December 30, 2019, the Company recorded approximately \$62,000 of related party expense for services provided by Pharma Hub Network.

NOTE 8 - LICENSING AGREEMENTS

Les Laboratories Servier

As a result of the Asset Purchase Agreement that the Company entered into with Symplmed Pharmaceuticals LLC in June 2017, Symplmed assigned to the Company an Amended and Restated License and Commercialization Agreement with Les Laboratories Servier, pursuant to which the Company has the exclusive right to manufacture, have manufactured, develop, promote, market, distribute and sell Prestalia® in the U.S. (and its territories and possessions). The terms of the agreement include single-digit royalty payments based on net sales and milestone payments based upon the attainment of sales thresholds. The agreement includes a termination clause pursuant to which Servier has the right to terminate the agreement in various circumstances, including, without limitation, as a result of the failure by the Company to achieve certain sales thresholds by the dates set forth in the agreement.

On November 19, 2019, the Company entered into an Amendment No. 4 to the Amended and Restated License and Commercialization Agreement with Les Laboratories Servier, which modified the agreement to delay the date by which the Company would be required to meet certain net sales milestones as set forth in the agreement. As per the license and commercialization agreement, as amended, Les Laboratories Servier may terminate the agreement if net sales of Prestalia® by the Company are below \$1.0 million for two successive calendar quarters beginning after June 30, 2020.

On January 4, 2021, Servier terminated the licensing agreement with the Company for the commercialization of Prestalia®.

For the year ended December 31, 2019 the Company paid \$37,000 for royalties under the license agreement with Servier. No royalties were paid for the year ended December 31, 2020.

Biofarma

As consideration for the Prestalia® Trademark license which the Company assumed in connection with the Asset Purchase Agreement with Symplmed, the Company pays low single digit royalties to Biofarma, an affiliate of Servier and the holder of the Prestalia trademark.

For the year ended December 31, 2019, the Company paid \$4,000 for royalties under the agreement with Biofarma. No royalties were paid for the year ended December 31, 2020.

Sub-License of DiLA² Assets

On March 16, 2018, the Company entered into an exclusive sub-licensing agreement for certain intellectual property rights to its DiLA² delivery system. The agreement included an upfront payment of \$200,000 and future additional consideration for sales and development milestones. The upfront fee was contingent upon the Company obtaining a third-party consent to the agreement within ninety days of execution. On November 30, 2019, the sub-licensing agreement was terminated. As of December 31, 2020, and 2019, the Company has classified the upfront payment as an accrued liability on its balance sheet.

Novosom Agreements

In 2010, the Company entered into an asset purchase agreement with Novosom Verwaltungs GmbH (“Novosom”), pursuant to which the Company acquired intellectual property for Novosom’s SMARTICLES-based liposomal delivery system. In May 2018, the Company issued to Novosom 51,988 shares of our common stock, with a fair value of \$75,000, as additional consideration pursuant to the Asset Purchase Agreement. Such shares were due to Novosom as a result of the receipt by our company of a license fee under the License Agreement that we entered into with Lipomedics Inc. in February 2017. On December 23, 2019, Novosom repurchased the acquired intellectual property for \$45,000 of which \$20,000 was payable upon execution of the agreement and \$25,000 was to be paid upon the Company’s achievement of certain performance obligations by June 30, 2020.

The Company recognized \$20,000 and \$25,000 as other income from the agreement for the year ended December 31, 2019 and 2020, respectively.

NOTE 9 - STOCKHOLDERS' EQUITY*Preferred Stock*

Adhera has authorized 100,000 shares of preferred stock for issuance and has designated 1,000 shares as Series B Preferred Stock ("Series B Preferred") and 90,000 shares as Series A Junior Participating Preferred Stock ("Series A Preferred"). No shares of Series B Preferred or Series A Preferred are outstanding. In March 2014, Adhera designated 1,200 shares as Series C Convertible Preferred Stock ("Series C Preferred"). In August 2015, Adhera designated 220 shares as Series D Convertible Preferred Stock ("Series D Preferred"). In April 2018, Adhera designated 3,500 shares of Series E Convertible Preferred Stock ("Series E Preferred"). In July 2018, Adhera designated 2,200 shares of Series F Convertible Preferred Stock ("Series F Preferred").

Series C Preferred

Each share of Series C Preferred has a stated value of \$5,000 per share, has a \$5,100 liquidation preference per share, has voting rights of 666.67 votes per share, and is convertible into shares of common stock at a conversion price of \$7.50 per share.

As of December 31, 2020, and December 31, 2019, 100 shares of Series C Preferred stock were outstanding.

Series D Preferred

Each share of Series D Preferred has a stated value of \$5,000 per share, has a liquidation preference of \$300 per share, has voting rights of 1,250 votes per share and is convertible into shares of common stock at a conversion price of \$4.00 per share. The Series D Preferred has a 5% stated dividend rate when, and if declared by the Board of Directors, is not redeemable and has voting rights on an as-converted basis.

As of December 31, 2020, and December 31, 2019, 40 shares of Series D Preferred were outstanding.

Series E Convertible Preferred Stock Private Placement

In April and May 2018, the Company entered into Subscription Agreements with certain accredited investors and conducted a closing pursuant to which we sold 2,812 shares of our Series E Preferred, at a purchase price of \$5,000 per share of Series E Preferred. Each share of Series E Preferred is initially convertible into shares of our common stock at a conversion price of \$0.50 per share of common stock. In addition, each investor received a 5-year warrant to purchase 0.75 shares of common stock for each share of common stock issuable upon the conversion of the Series E Preferred purchased by such investor at an initial exercise price equal to \$0.55 per share of common stock, subject to adjustment thereunder. In July of 2018, the exercise price of the warrants was adjusted down to \$0.50 upon issuance of the Series F Convertible Preferred Stock.

The Series E Preferred accrues 8% dividends per annum and are payable in cash or stock at the Company's discretion. The Series E Preferred has voting rights, dividend rights, liquidation preferences, conversion rights and anti-dilution rights as described in the Certificate of Designation of Preferences, Rights and Limitations of the Preferred Stock, which we filed with the Secretary of State of Delaware in April 2018. The Warrants have full-ratchet anti-dilution protection, are exercisable for a period of five years and contain customary exercise limitations.

The Company received net proceeds of approximately \$12.2 million from the sale of the Series E Preferred, after deducting placement agent fees and estimated expenses payable by us of approximately \$2.0 million associated with such closing. In connection with the private placement described above, we also issued to the placement agent for such private placement a Warrant to purchase 2,958,460 shares of our common stock.

In October 2018, an investor converted 2 shares of Series E Preferred into 20,000 shares of our common stock.

In April 2019, the Company issued 107,846 unregistered shares of our common stock to a holder of Series E Convertible Preferred Stock in connection with the conversion of 10 shares Series E Convertible Preferred Stock plus accrued dividends.

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On December 11, 2020, the Company issued 121,699 unregistered shares of our common stock to a holder of Series E Convertible Preferred Stock in connection with the conversion of 10 shares Series E Convertible Preferred Stock plus accrued dividends.

On December 21, 2020, the Company issued 121,480 unregistered shares of our common stock to a holder of Series E Convertible Preferred Stock in connection with the conversion of 10 shares Series E Convertible Preferred Stock plus accrued dividends.

The Company had accrued dividends on the Series E Preferred stock of approximately \$3.7 and \$2.4 million for the years ended December 31, 2020 and December 31, 2019, respectively.

Series F Convertible Preferred Share Private Placement

In July 2018, we entered into Subscription Agreements with certain accredited investors and conducted a closing pursuant to which we sold 308 shares of our Series F Preferred, at a purchase price of \$5,000 per share of Series F Preferred. Each share of Series F Preferred is initially convertible into shares of our common stock at a conversion price of \$0.50 per share of common stock. In addition, each investor received a 5-year warrant (the “Warrants”, and collectively with the Preferred Stock, the “Securities”) to purchase 0.75 shares of common stock for each share of common stock issuable upon the conversion of the Series F Preferred purchased by such investor at an initial exercise price equal to \$0.55 per share of common stock, subject to adjustment thereunder. The Series F Preferred accrues 8% dividends per annum and are payable in cash or stock at the Company’s discretion. The Series F Preferred has voting rights, dividend rights, liquidation preferences, conversion rights and anti-dilution rights as described in the Certificate of Designation of Preferences, Rights and Limitations of the Preferred Stock, which we filed with the Secretary of State of Delaware in July 2018. The Warrants have full-ratchet anti-dilution protection, are exercisable for a period of five years and contain customary exercise limitations.

We received proceeds of approximately \$1.4 million from the sale of the Securities, after deducting placement agent fees and estimated expenses payable by us of approximately \$180,000 associated with such closing. In connection with the private placement described above, we also issued to the placement agent for such private placement a warrant to purchase 308,000 shares of our common stock. The warrant has a five-year term and an exercise price of \$0.55 per share.

On November 9, 2018, the Company entered into Subscription Agreements with certain accredited investors and conducted a closing pursuant to which we sold 73 shares of our Series F Preferred Stock, at a purchase price of \$5,000 per share of Preferred Stock. In addition, each investor received a 5-year warrant to purchase 0.75 shares of common stock for each share of common stock issuable upon the conversion of the Series F Preferred purchased by such investor at an initial exercise price equal to \$0.55 per share of common stock, subject to adjustment thereunder. The Company received total net proceeds of approximately \$0.31 million from the issuance of the securities described above, after deducting placement agent fees and estimated expenses payable by us associated with such closing. In connection with the private placement described above, the Company also issued to the placement agent for such private placement a Warrant to purchase 73,000 shares of our common stock. The warrant has a five-year term and an exercise price of \$0.55 per share.

On October 30, 2019, the Company repurchased 20 shares of Series F Convertible Preferred Stock including accrued and unpaid dividends and warrants to purchase 150,000 shares of common stock for \$100,000 from our former

CEO pursuant to an amendment to the settlement agreement dated April 4, 2019. The Company also committed to purchase from such officer the remaining Series F Convertible Preferred Stock and related warrants held by such officer for \$100,000 by not later than March 1, 2020. As of December 31, 2020, the Company had not repurchased the remaining shares.

The Company had accrued dividends on the Series F Preferred stock of approximately \$347,000 and \$202,000, respectively for the years ended December 31, 2020 and December 31, 2019, respectively.

Common Stock

The Company's common stock currently trades on the OTC Pink Sheets tier of the OTC Markets under the symbol "ATRX". As of December 31, 2020, the Company had 11,112,708 shares of our common stock outstanding.

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Warrants

As of December 31, 2020, there were 78,181,855 warrants outstanding, with a weighted average exercise price of \$0.26 per share, and annual expirations as follows:

	Warrants
Expiring in 2021	343,750
Expiring in 2022	—
Expiring in 2023	33,645,847
Expiring in 2024	335,452
Expiring in 2025	43,856,806
	<u>78,181,855</u>

The above includes 77,489,372 price adjustable warrants, including 42,266,304 warrants issued with the February 5, 2020 term loan and 1,587,301 warrants issued with the October 30, 2020 term loans which are subject to adjustment based upon the final conversion price of the note.

A total of 1,189,079 warrants expired during the year ended December 31, 2020.

NOTE 10 - STOCK INCENTIVE PLANS

Stock Options

The following table summarizes stock option activity for the year ended December 31, 2020 and 2019:

	Options Outstanding	
	Shares	Weighted Average Exercise Price
Outstanding, December 31, 2018	5,613,057	\$ 0.83
Options granted	1,985,000	0.35
Options expired / forfeited	(3,526,724)	0.76
Outstanding, December 31, 2019	4,071,333	\$ 0.58
Options granted	—	—
Options expired / forfeited	(3,679,983)	0.53
Outstanding, December 31, 2020	<u>391,350</u>	<u>\$ 1.00</u>
Exercisable, December 31, 2020	<u>391,350</u>	<u>\$ 1.00</u>

During the year ended December 31, 2019, the Company granted an aggregate of 1,985,000 stock options to employees at exercise prices ranging from \$0.09 to \$0.37 per share with a 10-year term. A total of 575,000 options were immediately vested and 550,000 options were performance based options that were contingent upon the Company meeting certain sales and stock-price target goals. All of the performance based options were forfeited on December 31, 2019.

The following table summarizes additional information on the Company's stock options outstanding at December 31, 2020:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted- Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$0.98 - \$1.00	383,500	2.32	\$ 0.98	383,500	\$ 0.98
\$1.70	4,050	1.02	\$ 1.70	4,050	\$ 1.70
\$2.60	3,800	0.01	\$ 2.60	3,800	\$ 2.60
Totals	391,350	2.29	\$ 1.00	391,350	\$ 1.00

No stock options were issued by the Company during the year ended December 31, 2020.

As of December 31, 2020, the Company had no unrecognized compensation expense related to unvested stock options. Total expense related to stock options was approximately \$8,000 and \$765,000 for the years ended December 31, 2020 and 2019, respectively.

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As of December 31, 2020, the intrinsic value of options outstanding or exercisable was \$0 as there were no options outstanding with an exercise price less than \$0.04, the per share closing market price of our common stock at that date.

NOTE 11 - COMMITMENTS AND CONTINGENCIES

Litigation

Because of the nature of our activities, we are subject to claims and/or threatened legal actions, which arise out of the normal course of business. Other than the disclosure below, as of the date of this filing, we are not aware of any pending lawsuits against us, our officers or our directors.

Leases

On December 9, 2019, the Company entered into a Standard Form Office Lease with ThreeCo Partners, LLC as landlord, pursuant to which the Company leased its corporate headquarters located at 4815 Emperor Boulevard, Suite 100, Durham, North Carolina 27703 for a term of 19 months commencing January 1, 2020. The base monthly rent for such space was \$3,795. On February 1, 2020, the Company terminated the lease for a one-time cash payment of \$10,000. In addition, the Company recognized approximately \$19,000 in rent expense from a forfeited prepaid security deposit as a result of the termination.

Other than as described above, the Company does not own or lease any real property or facilities that are material to its current business operations. If the Company continues its business operations, the Company may seek to lease additional facilities in order to support its operational and administrative needs.

NOTE 12 - INCOME TAXES

The Company has identified its federal and California and North Carolina state tax returns as “major” tax jurisdictions. The periods the Company’s income tax returns are subject to examination for these jurisdictions are 2017 through 2020. The Company believes its income tax filing positions and deductions will be sustained on audit and does not anticipate any adjustments that would result in a material change to our financial position. Therefore, no liabilities for uncertain income tax positions have been recorded.

At December 31, 2020, the Company had available net operating loss carry-forwards for federal income tax reporting purposes of approximately \$348 million, which are available to offset future taxable income. Portions of these carry-forwards will expire through 2039 if not otherwise utilized. The Company has not performed a formal analysis but believes its ability to use such net operating losses and tax credit carry-forwards is subject to annual limitations due to change of control provisions under Sections 382 and 383 of the Internal Revenue Code, which significantly impacts its ability to realize these deferred tax assets.

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The Company’s net deferred tax assets, deferred tax liabilities and valuation allowance as of December 31, 2020 and 2019 are summarized as follows:

(in thousands)	Years Ended December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	\$ 7,741	\$ 6,862
Inventory reserve	114	114
Depreciation and amortization	2,226	2,512
Share based compensation	599	597
Other	297	279
Total deferred tax assets	10,977	10,364
Valuation allowance	(10,977)	(10,364)
Net deferred tax assets	—	—
Deferred tax liabilities:		
Intangible assets	—	—
Net deferred tax liabilities	\$ —	\$ —

The Company records a valuation allowance in the full amount of our net deferred tax assets since realization of such tax benefits has been determined by our management to be less likely than not. The valuation allowance increased \$0.6 million and \$2.8 million during 2020 and 2019, respectively.

As of the date of this filing, the Company has not filed its 2019 or 2020 federal and state corporate income tax returns. The Company expects to file the 2019 return in the second quarter of 2021 and the 2020 return by the extension due date.

NOTE 13 - SUBSEQUENT EVENTS

Except for the events discussed below, there were no subsequent events that required recognition or disclosure. The Company evaluated subsequent events through the date the financial statements were issued and filed with the Securities and Exchange Commission.

Bridge Loan

On January 31, 2021, the Company issued to an existing investor in and lender to the Company a 10% original issue discounted Senior Secured Convertible Promissory Note for a purchase price of \$52,778. Additionally, the Company issued to the investor 753,968 warrants to purchase the Company's common stock at an exercise price of \$0.08 per share.

Pursuant to the Note, the Company promises to pay the principal sum of the Note to the noteholder on the date that is the six-month anniversary of the original issue date, or such earlier date as the Note is required or permitted to be repaid as provided thereunder, and to pay interest to the noteholder on the aggregate unconverted and then outstanding principal amount of the Note in accordance with the provisions thereof. Interest shall accrue on the aggregate unconverted and then outstanding principal amount of the Note at the rate of 10% per annum, calculated based on a 360-day year and shall accrue daily commencing on the original issue date until payment in full of the outstanding principal, together with all accrued and unpaid interest, liquidated damages and other amounts which may become due thereunder, has been made.

The Note is convertible, in whole or in part, at any time, and from time to time, into shares of the common stock of the Company at the option of the noteholder at a conversion price of \$0.07 (as adjusted for stock splits, stock combinations and similar events); provided, that if an event of default has occurred under the Note, then the conversion price shall be 70% of the then conversion price. The conversion price shall also be adjusted upon subsequent equity sales by the Company. The obligations of the Company under the Note are secured by a senior lien and security interest in all assets of the Company.

Conversion of Interest on Convertible Note

On March 19, 2021, \$29,500 of interest on the February 5, 2020 term loan was converted at \$0.05 per share into 518,000 shares of common stock.

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Exhibit 21.1

List of Subsidiaries

Name	State of Incorporation	Ownership
IthenaPharma Inc.	Delaware	100%
Cequent Pharmaceuticals, Inc.	Delaware	100%
MDRNA Research, Inc.	Delaware	100%
Atossa HealthCare, Inc.	Delaware	100%

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement on Form S-8 (File No. 333-231219), on Form S-8 (File No. 333-200836), and on Form S-8 (File No. 33-222416) of Adhera Therapeutics, Inc. of our report dated April 7, 2021, relating to the consolidated financial statements of Adhera Therapeutics, Inc. (which expresses an unqualified opinion and includes an explanatory paragraph relating to the Company's ability to continue as a going concern), appearing in this current report on Form 10-K for the years ended December 31, 2020 and 2019.

/s/ Baker Tilly US, LLP

**ADHERA THERAPEUTICS, INC.
PURSUANT TO SECTION 302**

I, Andrew Kucharchuk, certify that:

1. I have reviewed this Annual Report on Form 10-K of Adhera Therapeutics, Inc. for the year ended December 31, 2020;
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. I am 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. 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: April 7, 2021

By: /s/ Andrew Kucharchuk

Name: Andrew Kucharchuk

Title: Chief Executive Officer (Principal Executive Officer and Principal Financial Officer)

Exhibit 32.1

**ADHERA THERAPEUTICS, INC.
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with this Annual Report on Form 10-K of Adhera Therapeutics, Inc. (the "Company") for the year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, in the capacity and on the date indicated below, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to her knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

Date: April 7, 2021

By: /s/ Andrew Kucharchuk

Name: Andrew Kucharchuk

Title: Chief Executive Officer (Principal Executive Officer and Principal Financial Officer)
