

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

FORM C-AR

UNDER THE SECURITIES ACT OF 1933

- ☐ Form C: Offering Statement
- ☐ Form C-U: Progress Update
- ☐ Form C/A: Amendment to Offering Statement
 - ☐ Check box if Amendment is material and investors must reconfirm within five business days.
- ☒ Form C-AR: Annual Report
- ☐ Form C-AR/A: Amendment to Annual Report
- ☐ Form C-TR: Termination of Reporting

Name of issuer

Hera Health Solutions, Inc.

Legal status of issuer

Form

Corporation

Jurisdiction of Incorporation/Organization

Delaware

Date of organization

May 22, 2017

Physical address of issuer

11141 Wellshire Ln.
Frisco, TX 75035

Website of issuer

www.herahealthsolutions.com

Current number of employees

4

	Most recent fiscal year-end	Prior fiscal year-end
Total Assets	\$670,295	\$831,820
Cash & Cash Equivalents	\$670,295	\$831,820
Accounts Receivable	0	0
Short-term Debt	\$129,591	\$87,466
Long-term Debt	0	0
Revenues/Sales	0	0
Cost of Goods Sold	0	0
Taxes Paid	0	0
Net Income	-\$203,650	-\$148,081

April 21, 2021

FORM C-AR

Hera Health Solutions Inc.



This Form C-AR (including the cover page and all exhibits attached hereto, the "Form C-AR") is being furnished by Hera Health Solutions Inc., a Delaware Corporation (the "Company," as well as references to "we," "us," or "our"), for the sole purpose of providing certain information about the Company as required by the Securities and Exchange Commission ("SEC").

No federal or state securities commission or regulatory authority has passed upon the accuracy or adequacy of this document. The U.S. Securities and Exchange Commission does not pass upon the accuracy or completeness of any disclosure document or literature. The Company is filing this Form C-AR pursuant to Regulation CF (§ 227.100 et seq.) which requires that it must file a report with the Commission annually and post the report on its website at www.herahealthsolutions.com no later than 120 days after the end of each fiscal year covered by the report. The Company may terminate its obligations in the future in accordance with Rule 202(b) of Regulation CF (§ 227.202(b)) by 1) being required to file reports under Section 13(a) or Section 15(d) of the Exchange Act of 1934, as amended, 2) filing at least one annual report pursuant to Regulation CF and having fewer than 300 holders of record, 3) filing annual reports for 3 years pursuant to Regulation CF and having assets equal to or less than \$10,000,000, 4) the repurchase of all the Securities sold pursuant to Regulation CF by the Company or another party, or 5) the liquidation or dissolution of the Company.

The date of this Form C-AR is April 21, 2021.

THIS FORM C-AR DOES NOT CONSTITUTE AN OFFER TO PURCHASE OR SELL SECURITIES.

Forward Looking Statement Disclosure

This Form C-AR and any documents incorporated by reference herein or therein contain forward-looking statements and are subject to risks and uncertainties. All statements other than statements of historical fact or relating to present facts or current conditions included in this Form C-AR are forward-looking statements. Forward-looking statements give the Company's current reasonable expectations and projections relating to its financial condition, results of operations, plans, objectives, future performance and business. You can identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. These statements may include words such as "anticipate," "estimate," "expect," "project," "plan," "intend," "believe," "may," "should," "can have," "likely" and other words and terms of similar meaning in connection with any discussion of the timing or nature of future operating or financial performance or other events.

The forward-looking statements contained in this Form C-AR and any documents incorporated by reference herein or therein are based on reasonable assumptions the Company has made in light of its industry experience, perceptions of historical trends, current conditions, expected future developments and other factors it believes are appropriate under the circumstances. As you read and consider this Form C-AR, you should understand that these statements are not guarantees of performance or results. They involve risks, uncertainties (many of which are beyond the Company's control) and assumptions. Although the Company believes that these forward-looking statements are based on reasonable assumptions, you should be aware that many factors could affect its actual operating and financial performance and cause its performance to differ materially from the performance anticipated in the forward-looking statements. Should one or more of these risks or uncertainties materialize, or should any of these assumptions prove incorrect or change, the Company's actual operating and financial performance may vary in material respects from the performance projected in these forward-looking statements.

Any forward-looking statement made by the Company in this Form C-AR or any documents incorporated by reference herein or therein speaks only as of the date of this Form C-AR. Factors or events that could cause our actual operating and financial performance to differ may emerge from time to time, and it is not possible for the Company to predict all of them. The Company undertakes no obligation to update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by law.

ONGOING REPORTING

The Company will file a report electronically with the Securities & Exchange Commission annually and post the report on its website, no later than 120 days after the end of the Company's fiscal year.

Once posted, the annual report may be found on the Company's website at: www.herahealthsolutions.com

The Company must continue to comply with the ongoing reporting requirements until:

(1) the Company is required to file reports under Section 13(a) or Section 15(d) of the Exchange Act;

- (2) the Company has filed at least three annual reports pursuant to Regulation CF and has total assets that do not exceed \$10,000,000;
- (3) the Company has filed at least one annual report pursuant to Regulation CF and has fewer than 300 holders of record;
- (4) the Company or another party repurchases all of the Securities issued in reliance on Section 4(a)(6) of the Securities Act, including any payment in full of debt securities or any complete redemption of redeemable securities; or
- (5) the Company liquidates or dissolves its business in accordance with state law.

About this Form C-AR

You should rely only on the information contained in this Form C-AR. We have not authorized anyone to provide you with information different from that contained in this Form C-AR. You should assume that the information contained in this Form C-AR is accurate only as of the date of this Form C-AR, regardless of the time of delivery of this Form C-AR. Our business, financial condition, results of operations, and prospects may have changed since that date. Statements contained herein as to the content of any agreements or other document are summaries and, therefore, are necessarily selective and incomplete and are qualified in their entirety by the actual agreements or other documents.

SUMMARY

The following summary is qualified in its entirety by more detailed information that may appear elsewhere in this Form C-AR and the Exhibits hereto.

Hera Health Solutions Inc. (the "Company") is a Delaware Corporation, formed on May 22, 2017.

The Company is located at 11141 Wellshire Ln., Frisco, TX 75035.

The Company's website is www.HeraHealthSolutions.com.

The information available on or through our website is not a part of this Form C-AR.

The Business

Hera Health Solutions is a pharmaceutical device company that specializes in the development and commercialization of long acting treatments through proprietary biodegradable implants. Hera Health intends to sell its first product, the contraceptive biodegradable implant Eucontra, to OB/GYN practices as well as family planning clinics in the U.S. market. Internationally, the Company will seek to sell to nonprofit organizations and large-scale Non-Governmental Organizations (NGOs) that distribute contraceptives to countries with a limited access to healthcare. It also intends to price Eucontra at \$800 per device, which the Company believes is competitive with its alternative, Nexplanon. The executive team estimates a 98.5% gross margin for retail sales but intends to heavily subsidize Eucontra for bulk distribution to humanitarian partners.

RISK FACTORS

Risks Related to the Company's Business and Industry

In order for the Company to compete and grow, it must attract, recruit, retain and develop the necessary personnel who have the needed experience.

Recruiting and retaining highly qualified personnel is critical to our success. These demands may require us to hire additional personnel and will require our existing management personnel to develop additional expertise. We face intense competition for personnel. The failure to attract and retain personnel or to develop such expertise could delay or halt the development and commercialization of our product candidates. If we experience difficulties in hiring and retaining personnel in key positions, we could suffer from delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect operating results. Our consultants and advisors may be employed by third parties and may have commitments under consulting or advisory contracts with third parties that may limit their availability to us.

Quality management plays an essential role in determining and meeting customer requirements, preventing defects, improving the Company's products and services and maintaining the integrity of the data that supports the safety and efficacy of our products.

Our future success depends on our ability to maintain and continuously improve our quality management program. An inability to address a quality or safety issue in an effective and timely manner may also cause negative publicity, a loss of customer confidence in us or our current or future products, which may result in the loss of sales and difficulty in successfully launching new products. In addition, a successful claim brought against us in excess of available insurance or not covered by indemnification agreements, or any claim that results in significant adverse publicity against us, could have an adverse effect on our business and our reputation.

We may implement new lines of business or offer new products and services within existing lines of business.

There are substantial risks and uncertainties associated with these efforts, particularly in instances where the markets are not fully developed. In developing and marketing new lines of business and/or new products and services, we may invest significant time and resources. Initial timetables for the introduction and development of new lines of business and/or new products or services may not be achieved and price and profitability targets may not prove feasible. We may not be successful in introducing new products and services in response to industry trends or developments in technology, or those new products may not achieve market acceptance. As a result, we could lose business, be forced to price products and services on less advantageous terms to retain or attract clients or be subject to cost increases. As a result, our business, financial condition or results of operations may be adversely affected.

The Company's success depends on the experience and skill of the board of directors, its executive officers and key employees.

In particular, the Company is dependent on Idicula Mathew and Garrett Whitfield who are CEO and COO of the Company. The Company has or intends to enter into employment agreements with Idicula Mathew and Garrett Whitfield although there can be no assurance that it will do so or that they will continue to be employed by the Company for a particular period of time. The loss of Idicula Mathew and Garrett Whitfield or any member of the board of directors or executive officer could harm the Company's business, financial condition, cash flow and results of operations.

We rely on various intellectual property rights, including patents in order to operate our business.

Such intellectual property rights, however, may not be sufficiently broad or otherwise may not provide us a significant competitive advantage. In addition, the steps that we have taken to maintain and protect our intellectual property may not prevent it from being challenged, invalidated, circumvented or designed-around, particularly in countries where intellectual property rights are not highly developed or protected. In some circumstances, enforcement may not be

available to us because an infringer has a dominant intellectual property position or for other business reasons, or countries may require compulsory licensing of our intellectual property. Our failure to obtain or maintain intellectual property rights that convey competitive advantage, adequately protect our intellectual property or detect or prevent circumvention or unauthorized use of such property, could adversely impact our competitive position and results of operations. We also rely on nondisclosure and noncompetition agreements with employees, consultants and other parties to protect, in part, trade secrets and other proprietary rights. There can be no assurance that these agreements will adequately protect our trade secrets and other proprietary rights and will not be breached, that we will have adequate remedies for any breach, that others will not independently develop substantially equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets or other proprietary rights.

As we expand our business, protecting our intellectual property will become increasingly important. The protective steps we have taken may be inadequate to deter our competitors from using our proprietary information. In order to protect or enforce our patent rights, we may be required to initiate litigation against third parties, such as infringement lawsuits. Also, these third parties may assert claims against us with or without provocation. These lawsuits could be expensive, take significant time and could divert management's attention from other business concerns. The law relating to the scope and validity of claims in the technology field in which we operate is still evolving and, consequently, intellectual property positions in our industry are generally uncertain. We cannot assure you that we will prevail in any of these potential suits or that the damages or other remedies awarded, if any, would be commercially valuable.

From time to time, third parties may claim that one or more of our products or services infringe their intellectual property rights.

Any dispute or litigation regarding patents or other intellectual property could be costly and time-consuming due to the complexity of our technology and the uncertainty of intellectual property litigation and could divert our management and key personnel from our business operations. A claim of intellectual property infringement could force us to enter into a costly or restrictive license agreement, which might not be available under acceptable terms or at all, could require us to redesign our products, which would be costly and time-consuming, and/or could subject us to an injunction against development and sale of certain of our products or services. We may have to pay substantial damages, including damages for past infringement if it is ultimately determined that our products infringe on a third party's proprietary rights. Even if these claims are without merit, defending a lawsuit takes significant time, may be expensive and may divert management's attention from other business concerns. Any public announcements related to litigation or interference proceedings initiated or threatened against us could cause our business to be harmed. Our intellectual property portfolio may not be useful in asserting a counterclaim, or negotiating a license, in response to a claim of intellectual property infringement. In certain of our businesses we rely on third party intellectual property licenses and we cannot ensure that these licenses will be available to us in the future on favorable terms or at all.

Although dependent on certain key personnel, the Company does not have any key man life insurance policies on any such people.

The Company is dependent on Idicula Mathew and Garrett Whitfield in order to conduct its operations and execute its business plan, however, the Company has not purchased any insurance policies with respect to those individuals in the event of their death or disability. Therefore, if any of Idicula Mathew and Garrett Whitfield die or become disabled, the Company will not receive any compensation to assist with such person's absence. The loss of such person could negatively affect the Company and its operations.

We have not prepared any audited financial statements.

Therefore, you have no audited financial information regarding the Company's capitalization or assets or liabilities on which to make your investment decision. If you feel the information provided is insufficient, you should not invest in the Company.

We are subject to income taxes as well as non-income based taxes, such as payroll, sales, use, value-added, net worth, property and goods and services taxes, in the U.S.

Significant judgment is required in determining our provision for income taxes and other tax liabilities. In the ordinary course of our business, there are many transactions and calculations where the ultimate tax determination is uncertain. Although we believe that our tax estimates are reasonable: (i) there is no assurance that the final determination of tax audits or tax disputes will not be different from what is reflected in our income tax provisions, expense amounts for non-income based taxes and accruals and (ii) any material differences could have an adverse effect on our financial position and results of operations in the period or periods for which determination is made.

We are not subject to Sarbanes-Oxley regulations and lack the financial controls and safeguards required of public companies.

We do not have the internal infrastructure necessary, and are not required, to complete an attestation about our financial controls that would be required under Section 404 of the Sarbanes-Oxley Act of 2002. There can be no assurance that there are no significant deficiencies or material weaknesses in the quality of our financial controls. We expect to incur additional expenses and diversion of management's time if and when it becomes necessary to perform the system and process evaluation, testing and remediation required in order to comply with the management certification and auditor attestation requirements.

Changes in employment laws or regulation could harm our performance.

Various federal and state labor laws govern our relationship with our employees and affect operating costs. These laws include minimum wage requirements, overtime pay, healthcare reform and the implementation of the Patient Protection and Affordable Care Act, unemployment tax rates, workers' compensation rates, citizenship requirements, union membership and sales taxes. A number of factors could adversely affect our operating results, including additional government-imposed increases in minimum wages, overtime pay, paid leaves of absence and mandated health benefits, mandated training for employees, increased tax reporting and tax payment changing regulations from the National Labor Relations Board and increased employee litigation including claims relating to the Fair Labor Standards Act.

Successful development of our products is uncertain.

The product candidates that we expect to develop are based on processes and methodologies that are not currently widely employed. Our development of current and future product candidates are subject to the risks of failure and delay inherent in the development of new products and products based on new technologies, including delays in product development, clinical testing, or manufacturing; unplanned expenditures in product development, clinical testing, or manufacturing, a failure to receive regulatory approvals, the inability to manufacture on our own, or through any others, product candidates on a commercial scale, or failure to achieve market acceptance, and the emergence of superior or equivalent products.

Because of these risks, our research and development efforts may not result in any commercially viable products. If a significant portion of these development efforts are not successfully

completed, required regulatory approvals are not obtained, or any approved products are not commercially successfully, our business, financial condition, and results of operations may be materially harmed.

The Health Care Reform Law 2.3% excise tax on domestic sales of medical devices by manufacturers and importers beginning in 2013, and the fee on branded prescription drugs and biologics that was implemented in 2011, may adversely affect sales and cost of goods sold.

The Health Care Reform Law 2.3% excise tax on domestic sales of medical devices by manufacturers and importers beginning in 2013, and the fee on branded prescription drugs and biologics that was implemented in 2011, may adversely affect sales and cost of goods sold.

For example, (i) where we purchase medical devices from third-party manufacturers, the manufacturers may increase their prices to cover their payment of the excise tax and our costs to purchase such medical devices may therefore increase and (ii) where we manufacture medical devices or are the importer of record, our cost of goods sold may increase because we are subject to paying the excise tax. If either of these scenarios were to occur, then there could be an adverse impact to our results of operations and financial condition.

Political, economic and regulatory influences are subjecting the healthcare industry to potential fundamental changes that could substantially affect our results of operations.

Government and private sector initiatives to limit the growth of healthcare costs, including price regulation, competitive pricing, coverage and payment policies, comparative effectiveness of therapies, technology assessments and alternative payment models, are continuing in countries where we do business, including the U.S. These changes are causing the marketplace to put increased emphasis on the delivery of more cost-effective treatments. As a U.S. headquartered Company with significant sales in the U.S., this healthcare reform legislation will materially impact us. Certain provisions of the legislation will not be effective for a number of years and it is unclear what the full impact of the legislation will be. Provisions of this legislation, including Medicare provisions aimed at improving quality and decreasing costs, comparative effectiveness research, an independent payment advisory board, and pilot programs to evaluate alternative payment methodologies, could meaningfully change the way healthcare is developed and delivered, and may adversely affect our business and results of operations. Further, we cannot predict what healthcare programs and regulations will be ultimately implemented at the federal or state level, or the effect of any future legislation or regulation in the U.S. or internationally. However, any changes that lower reimbursements for our products, reduce medical procedure volumes or increase cost containment pressures on us or other participants in the healthcare industry could adversely affect our business and results of operations.

Changes to government health care programs that reduce payments under Medicare and Medicaid may negatively impact payments from commercial third-party payers.

The Healthcare Reform Law will result in increased state legislative and regulatory changes in order for states to comply with new federal mandates, such as the requirement to establish or participate in Exchanges and to participate in grants and other incentive opportunities. In its June 28, 2012 ruling, the U.S. Supreme Court struck down the portion of the Health Reform Law that would have allowed the Department of Health and Human Services to penalize states that do not implement the Medicaid expansion provisions with the loss of existing federal Medicaid funding. Thus, states may opt not to implement the expansion. In some cases, commercial third-party payors rely on all or portions of Medicare payment systems to determine payment rates. Current or future health care reform and deficit reduction efforts, changes in laws or regulations regarding government health care programs, other changes in the administration of government health care programs and changes to commercial third-party payers in response to health care reform and other

changes to government health care programs could have a material, adverse effect on our financial position and results of operations.

Products that we manufacture, source, distribute or market are required to comply with regulatory requirements.

To lawfully operate our businesses, we are required to hold permits, licenses and other regulatory approvals from, and to comply with operating and security standards of, governmental bodies. Failure to maintain or renew necessary permits, licenses or approvals, or noncompliance or concerns over noncompliance may result in suspension of our ability to distribute, import or manufacture products, product recalls or seizures, or criminal and civil sanctions and could have an adverse effect on our results of operations and financial condition.

The manufacture, distribution, marketing and use of our products are subject to extensive regulation and increased scrutiny by the Food and Drug Administration (FDA) and other regulatory authorities globally.

Any new product must undergo lengthy and rigorous testing and other extensive, costly and time-consuming procedures mandated by FDA and foreign regulatory authorities. Changes to current products may be subject to vigorous review, including additional 510(k) and other regulatory submissions, and approvals are not certain. Our facilities must be approved and licensed prior to production and remain subject to inspection from time to time thereafter. Failure to comply with the requirements of FDA or other regulatory authorities, including a failed inspection or a failure in our adverse event reporting system, could result in adverse inspection reports, warning letters, product recalls or seizures, monetary sanctions, injunctions to halt the manufacture and distribution of products, civil or criminal sanctions, refusal of a government to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals and licenses. Any of these actions could cause a loss of customer confidence in us and our products, which could adversely affect our sales and results of operations.

Federal and State Laws Pertaining to Healthcare Fraud and Abuse Could Adversely Affect Our Business.

We are subject to various federal and state laws targeting fraud and abuse in the healthcare industry, including anti-kickback laws, false claims laws, laws constraining the sales, marketing and other promotional activities of manufacturers of medical devices by limiting the kinds of financial arrangements we may enter into with physicians, hospitals, laboratories and other potential purchasers of medical devices, laws requiring the reporting of certain transactions between us and healthcare professionals and HIPAA, as amended by HITECH, which governs the conduct of certain electronic healthcare transactions and protects security and privacy of protected health information. Violations of these laws are punishable by criminal or civil sanctions, including substantial fines, imprisonment and exclusion from participation in government healthcare programs such as Medicare and Medicaid. Many of the existing requirements are new and have not been definitively interpreted by state authorities or courts, and available guidance is limited. Unless and until we are in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity, all of which could materially harm our business. In addition, changes in or evolving interpretations of these laws, regulations, or administrative or judicial interpretations, may require us to change our business practices or subject our business practices to legal challenges, which could have a material adverse effect on our business, financial condition and results of operations.

We may rely on a group of third-party distributors to effectively distribute our products outside the United States.

We may depend, in part, on medical device distributors for the marketing and selling of our products in most geographies outside of the U.S. We depend on these distributors' efforts to market our products, yet we are unable to control their efforts completely. These distributors typically sell a variety of other, non-competing products that may limit the resources they dedicate to selling our products. In addition, we are unable to ensure that our distributors comply with all applicable laws regarding the sale of our products. If our distributors fail to effectively market and sell our products, in full compliance with applicable laws, our operating results and business may suffer. Recruiting and retaining qualified third-party distributors and training them in our technology and product offerings require significant time and resources. To develop and expand our distribution, we must continue to scale and improve our processes and procedures that support our distributors. Further, if our relationship with a successful distributor terminates, we may be unable to replace that distributor without disruption to our business. If we fail to maintain relationships with our distributors, fail to develop new relationships with other distributors, including in new markets, fail to manage, train or incentivize existing distributors effectively, or fail to provide distributors with competitive products on attractive terms, or if these distributors are not successful in their sales efforts, our revenue may decrease and our operating results, reputation and business may be harmed.

The commercial success of our products will depend in part upon the level of reimbursement we receive from third parties for the cost of our products to users.

The commercial success of any product will depend, in part, on the extent to which reimbursement for the costs of our products and related treatments will be available from third-party payors such as government health administration authorities, private health insurers, managed care programs, and other organizations. Adequate third-party insurance coverage may not be available for us to establish and maintain price levels that are sufficient for us to continue our business or for realization of an appropriate return on investment in product development.

If we are unable to educate physicians on the safe and effective use of our products, we may be unable to achieve our expected growth.

An important part of our sales process includes the education of physicians on the safe and effective use of our products. There is a learning process for physicians to become proficient in the use of our products and it typically takes several procedures for a physician to become comfortable using the product. If a physician experiences difficulties during an initial procedure or otherwise, that physician may be less likely to continue to use our product, or to recommend it to other physicians. It is critical to the success of our commercialization efforts to educate physicians on the proper use of the product, and to provide them with adequate product support during clinical procedures. It is important for our growth that these physicians advocate for the benefits of our products in the broader marketplace. If physicians are not properly trained, they may misuse or ineffectively use our products. This may also result in unsatisfactory patient outcomes, patient injuries, negative publicity or lawsuits against us, any of which could have an adverse effect on our business.

We depend on fewer suppliers for our products and therefore we may be less able to negotiate price terms with suppliers.

In recent years, pharmaceutical suppliers have been subject to increasing consolidation. As a result, a small number of very large companies control a significant share of the market. Many healthcare organizations also have consolidated to create larger healthcare enterprises with greater market power. If this consolidation trend continues, it could reduce the size of our target market and give the resulting enterprises greater bargaining power, which may lead to a decrease in the prices for our products and services.

If third-party payors do not provide adequate coverage and reimbursement for the use of our products, our revenues will be negatively impacted.

Our success in marketing our products depends in large part on whether U.S. and international government health administrative authorities, private health insurers and other organizations will adequately cover and reimburse customers for the cost of our products. In the United States, a third-party payor's decision to provide coverage for our products does not imply that an adequate reimbursement rate will be obtained. Further, one third-party payor's decision to cover our products does not assure that other payors will also provide coverage for the products or provide coverage at an adequate reimbursement rate. Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. In many international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Further, many international markets have government-managed healthcare systems that control reimbursement for new devices and procedures. In most markets there are private insurance systems as well as government-managed systems. If sufficient coverage and reimbursement is not available for our current or future products, in either the United States or internationally, the demand for our products and our revenues will be adversely affected.

We face heavy government regulation, and FDA regulatory approval of our products is uncertain.

The research, testing, manufacturing and marketing of drug products such as those that we are developing are subject to extensive regulation by federal, state and local government authorities, including the FDA. To obtain regulatory approval of a product, we must demonstrate to the satisfaction of the applicable regulatory agency that, among other things, the product is safe and effective for its intended use. In addition, we must show that the manufacturing facilities used to produce the products are in compliance with current Good Manufacturing Practices regulations (cGMP). The process of obtaining FDA and other required regulatory approvals and clearances will require us to expend substantial time and capital. Despite the time and expense expended, regulatory approval is never guaranteed. The number of preclinical and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is in development for, and the requirements applicable to that particular drug candidate. The FDA can delay, limit or deny approval of a drug candidate for many reasons, including that a drug candidate may not be shown to be safe or effective, the FDA may not approve our manufacturing process, the FDA may interpret data from preclinical and clinical trials in different ways than we do, and the FDA may not meet, or may extend, the Prescription Drug User Fee Act date with respect to a particular New Drug Application ("NDA").

For example, if certain of our methods for analyzing our trial data are not accepted by the FDA, we may fail to obtain regulatory approval for our product candidates. Moreover, if and when our products do obtain marketing approval, the marketing, distribution and manufacture of such products would remain subject to extensive ongoing regulatory requirements. Failure to comply with applicable regulatory requirements could result in warning letters, fines, civil penalties, injunctions, recall or seizure of products, total or partial suspension of production, refusal of the government to grant future approvals, withdrawal of approvals, or criminal prosecution.

Any delay or failure by us to obtain regulatory approvals for our product candidates could diminish competitive advantages that we may attain and would adversely affect the marketing of our products. To date, we have not received regulatory approval to market any of our product candidates in any jurisdiction. Following regulatory approval of any of our drug candidates, we

will be subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize our potential products.

With regard to our drug candidates, if any are approved by the FDA or by another regulatory authority, we are held to extensive regulatory requirements over product manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping. Regulatory approvals may also be subject to significant limitations on the indicated uses or marketing of the drug candidates. Potentially costly follow-up or post-marketing clinical studies may be required as a condition of approval to further substantiate safety or efficacy, or to investigate specific issues of interest to the regulatory authority. Previously unknown problems with the drug candidate, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the drug, and could include withdrawal of the drug from the market.

In addition, the law or regulatory policies governing pharmaceuticals may change. New statutory requirements may be enacted or additional regulations may be enacted that could prevent or delay regulatory approval of our drug candidates. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or elsewhere. If we are not able to maintain regulatory compliance, we might not be permitted to market our drugs and our business could suffer.

We may in the future be subject to various U.S. federal and state laws pertaining to health care fraud and abuse, including anti-kickback, self-referral, false claims and fraud laws, and any violations by us of such laws could result in fines or other penalties.

If one or more of our product candidates is approved, we will likely be subject to the various U.S. federal and state laws intended to prevent health care fraud and abuse. The federal anti-kickback statute prohibits the offer, receipt, or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in whole or part by Medicare, Medicaid or other federal health care programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced price items and services. Many states have similar laws that apply to their state health care programs as well as private payers. Violations of the anti-kickback laws can result in exclusion from federal health care programs and substantial civil and criminal penalties.

The False Claims Act (FCA) imposes liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment by a federal health care program. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. The FCA includes a whistleblower provision that allows individuals to bring actions on behalf of the federal government and share a portion of the recovery of successful claims. If our marketing or other arrangements were determined to violate the FCA or anti-kickback or related laws, then our revenue could be adversely affected, which would likely harm our business, financial condition, and results of operations.

State and federal authorities have aggressively targeted medical technology companies for alleged violations of these anti-fraud statutes, based on improper research or consulting contracts with doctors, certain marketing arrangements that rely on volume-based pricing, off-label marketing schemes, and other improper promotional practices. Companies targeted in such prosecutions have paid substantial fines in the hundreds of millions of dollars or more, have been forced to implement extensive corrective action plans or Corporate Integrity Agreements, and have often become

subject to consent decrees severely restricting the manner in which they conduct their business. If we become the target of such an investigation or prosecution based on our contractual relationships with providers or institutions, or our marketing and promotional practices, we could face similar sanctions, which would materially harm our business.

If we are found to have violated laws protecting the privacy or security of patient health information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

There are a number of U.S. federal and state laws and foreign laws protecting the privacy and security of individually identifiable health information, or "protected health information" including patient records, and restricting the use and disclosure of that protected health information that we are subject to. In the United States, the U.S. Department of Health and Human Services promulgated health information privacy and security rules under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and then significantly strengthened and broadened the applicability of HIPAA under the Health Information Technology for Economic and Clinical Health Act (HITECH, together HIPAA). HIPAA applies to health care providers engaging in certain standard transactions electronically; health plans and health care clearing houses. These entities are referred to as "covered entities." Certain HIPAA provisions also apply to "business associates" of covered entities, or third party providers of services to covered entities that involve the use or disclosure of protected health information. HIPAA's privacy rules protect medical records and protected health information in all forms by limiting its use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting, in some circumstances, the use and disclosure of protected health information to the minimum amount reasonably necessary to accomplish the intended purpose of the use or disclosure. HIPAA's security standards require both covered entities and business associates to implement administrative, physical and technical security measures to maintain the security of protected health information in electronic form. Covered entities and business associates must conduct initial and ongoing risk assessments to ensure the ongoing effectiveness of security measures and maintain a written information security plan. We are a covered entity and as such, we must comply with HIPAA and ensure that all aspects of our operations comply with relevant HIPAA standards. We are subject to random audit by federal authorities, and enforcement by both state and federal regulators. We are also subject to investigation in response to complaints. If we are found to be in violation of the HIPAA requirements, we could be subject to civil or criminal penalties as well as fines, which could increase our liabilities and harm our reputation or our business.

Beyond HIPAA, most states have adopted data security laws protecting the personal data of state residents. Personal data subject to protection typically includes name coupled with social security number, state-issued identification number, or financial account number. Most states require specific, technical security measures for the protection of all personal data, including employee data, and impose their own breach notification requirements in the event of a loss of personal data. State data security laws generally overlap and apply simultaneously with HIPAA. Non-U.S. privacy protection requirements such as the European Union's Data Protection Directive governing the processing of personal data, may be stricter than the U.S. law and violation would impose similar or more severe penalties. These laws could create liability for us or increase our cost of doing business, and any failure to comply could result in harm to our reputation, and potentially fines and penalties.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the Affordable Care Act, was passed, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The Affordable Care Act, among other things, subjected biologic products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressures, which would negatively affect our business.

New product development involves a lengthy, expensive and complex process.

We may be unable to develop or commercialize any of the product candidates we are currently researching. Moreover, even if we develop such candidates, they may be subject to significant regulatory review, approval and other government regulations. We are currently conducting research and development on Eucontra for contraception. There can be no assurance that our technologies will be capable of reliably addressing resistant infections or that we can develop and commercialize our products at all. New product development involves a lengthy, expensive and complex process and we currently have no fully validated diagnostic candidates. In addition, before we can commercialize any new product candidates, we will need to conduct substantial research and development, conduct validation studies, expend significant funds, develop and scale-up our laboratory processes, and obtain regulatory approval and acceptance of our product candidates.

This process involves a high degree of risk and takes several years. Our product development efforts may fail for many reasons, including failure of the product at the research or development stage, and lack of clinical validation data to support the effectiveness of the product.

Few research and development projects result in commercial products, and perceived viability in early clinical trials often is not replicated in later studies. At any point, we may abandon development of a product candidate or we may be required to expend considerable resources repeating clinical trials, which would adversely impact the timing for generating potential revenues from those product candidates. In addition, as we develop product candidates, we will have to make significant investments in product development, marketing and sales resources.

We may not be able to conduct clinical trials necessary to commercialize and sell our proposed products and formulations.

In order to conduct clinical trials that are necessary to obtain approval by the FDA to market a formulation or product, it is necessary to receive clearance from the FDA to conduct such clinical trials. The FDA can halt clinical trials at any time for safety reasons or because we or our clinical

investigators do not follow the FDA's requirements for conducting clinical trials. If we are unable to receive clearance to conduct clinical trials or the trials are halted by the FDA, we would not be able to achieve any revenue from such product as it is illegal to sell any drug or medical device for human consumption without FDA approval. Moreover, it is our stated intention to attempt to avail ourselves of the FDA's Fast Track approval procedure, which we believe is less costly and time consuming. If this approval pathway is not available to us with respect to a particular formulation or product, or at all, the time and cost associated with developing and commercializing such formulations or products may be prohibitive and our business strategy would be materially and adversely affected.

Our long-term viability and growth will depend upon successful clinical trials.

Product development is very expensive and involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. Success in preclinical work or early stage clinical trials does not ensure that later stage or larger scale clinical trials will be successful. Conducting clinical trials is a complex, time-consuming and expensive process. Our ability to complete our clinical trials in a timely fashion depends in large part on a number of key factors including protocol design, regulatory and institutional review board approval, the rate of patient enrollment in clinical trials, and compliance with extensive current Good Clinical Practices. In addition, if another Company is the first to file for marketing approval of a competing orphan drug candidate, that Company may ultimately receive marketing exclusivity for its drug candidate, preventing us from commercializing our orphan drug candidate in the applicable market for several years.

We face significant competition from other biotechnology and pharmaceutical companies.

We are aware of several companies that are working to develop drugs that would compete against our drug candidates. Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of drug candidates, as well as in obtaining regulatory approvals of those drug candidates in the U.S. and in foreign countries. Our current and potential future competitors may also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small number of our competitors.

Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, drug candidates that are more effective or less costly than any drug candidate that we may develop.

Our ability to compete successfully will depend largely on our ability to discover, develop and commercialize drugs that are superior to other products in the market, demonstrate through our clinical trials that our drug candidates are differentiated from existing and future therapies, attract qualified scientific, product development and commercial personnel, obtain patent or other proprietary protection for our drugs and technologies, obtain required regulatory approvals, successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new drugs, and negotiate competitive pricing and reimbursement with third party payers

The availability of our competitors' products could limit the demand, and the price we are able to charge, for any drug candidate we develop. The inability to compete with existing or subsequently

introduced drug candidates would have a material adverse impact on our business, financial condition and prospects.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in license novel compounds that could make our drug candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing or receiving FDA approval for or commercializing medicines before we do, which would have a material adverse impact on our business.

Our research and development efforts may not succeed in developing commercially successful products and technologies, which may limit our ability to achieve profitability.

We must continue to explore opportunities that may lead to new products and technologies. To accomplish this, we must commit substantial efforts, funds, and other resources to research and development. A high rate of failure is inherent in the research and development of new products and technologies. Any such expenditures that we make will be made without any assurance that our efforts will be successful. Failure can occur at any point in the process, including after significant funds have been invested.

Regardless of whether our clinical trials are deemed to be successful, promising new product candidates may fail to reach the market or may only have limited commercial success because of efficacy or safety concerns, failure to achieve positive clinical outcomes, inability to obtain necessary regulatory approvals or satisfy regulatory criteria, limited scope of approved uses, excessive costs to manufacture, the failure to establish or maintain intellectual property rights, or infringement of the intellectual property rights of others.

Even if we successfully develop new products or enhancements, they may be quickly rendered obsolete by changing customer preferences, changing industry standards, or competitors' innovations. Innovations may not be quickly accepted in the marketplace because of, among other things, entrenched patterns of clinical practice or uncertainty over third-party reimbursement. We cannot state with certainty when or whether any of our products under development will be launched, whether we will be able to develop, license, or otherwise acquire drug candidates or products, or whether any products will be commercially successful. Failure to launch successful new products or new indications for existing products may cause our products to become obsolete, which may limit our ability to achieve profitability.

Even if we are able to obtain regulatory approvals for our new pharmaceutical products, generic or branded, the success of those products is dependent upon market acceptance.

Levels of market acceptance for our new products could be impacted by several factors, including but not limited to: i) the availability of alternative products from our competitors, ii) the price of our products relative to that of our competitors, iii) the timing of our market entry, iv) the ability to market our products effectively to the retail level and v) the acceptance of our products by government and private entities. Some of these factors are not within our control. Additionally, continuing studies of the proper utilization, safety and efficacy of pharmaceutical products are being conducted by the industry, government agencies and others. Such studies, which increasingly employ sophisticated methods and techniques, can call into question the utilization, safety and efficacy of previously marketed products. In some cases, studies have resulted, and may in the future result, in the discontinuance of product marketing or other risk management programs

such as the need for a patient registry. These situations, should they occur, could have a material adverse effect on our profitability, business, financial position and results of operations.

Our manufacturing activity is subject to certain risks.

We may manufacture the products sold to our customers in a location to be obtained in the future. As a result, we may be dependent upon the uninterrupted and efficient operation of our manufacturing facility and our distribution facilities throughout the country. Our manufacturing facilities and distribution facilities may be subject to the risk of catastrophic loss due to, among other things, earthquake, fire, flood, terrorism or other natural or man-made disasters, as well as occurrence of significant equipment failures. If any of these facilities were to experience a catastrophic loss, it would be expected to disrupt our operations and could result in personal injury or property damage, damage relationships with our customers or result in large expenses to repair or replace the facilities or systems, as well as result in other liabilities and adverse impacts.

We contract with third-party manufacturers to produce our products in accordance with our specifications and standards. These contract manufacturers are subject to the same risks as our manufacturing facility as noted above. While we have implemented stringent quality control procedures to verify that our contract manufacturers comply with our specifications and standards, we do not have full control over their manufacturing activities. Any difficulties, delays and defects in our products resulting from the activities of our contract manufacturers may have an adverse effect on our business and results of operations.

In addition, the occurrence of manufacturing-related compliance issues could require subsequent withdrawal of the drug approval, reformulation of the drug product, additional testing or changes in labeling of the finished product. Any delay, interruption or cessation of production by our third-party manufacturers or strategic partners of our commercial products or product candidates, or their respective materials and components, as a result of any of the above factors or otherwise, may limit our ability to meet demand for commercial products and/or delay ongoing clinical trials, either of which could have a material adverse effect on our business, results of operations and financial condition.

We could experience difficulties and delays in the manufacturing, distribution and sale of our products.

Our product supply and related patient access could be negatively impacted by, among other things: (i) product seizures or recalls or forced closings of manufacturing plants; (ii) disruption in supply chain continuity including from natural or man-made disasters at one of our facilities or at a critical supplier, as well as our failure or the failure of any of our suppliers to comply with Current Good Manufacturing Practices and other applicable regulations or quality assurance guidelines that could lead to manufacturing shutdowns, product shortages or delays in product manufacturing; (iii) manufacturing, quality assurance/quality control, supply problems or governmental approval delays; (iv) the failure of a sole source or single source supplier to provide us with the necessary raw materials, supplies or finished goods within a reasonable timeframe; (v) the failure of a third-party manufacturer to supply us with bulk active or finished product on time; (vi) construction or regulatory approval delays for new facilities or the expansion of existing facilities, including those intended to support future demand for our biologics products; (vii) the failure to meet new and emerging regulations requiring products to be tracked throughout the distribution channels using unique identifiers to verify their authenticity in the supply chain; and (viii) other manufacturing or distribution issues, including limits to manufacturing capacity due to regulatory requirements, and changes in the types of products produced, such as biologics, physical limitations or other business interruptions, any of which could have a negative effect on our business and results of operations.

Increased concerns over the safety of our products may result in negative publicity or increased regulatory controls on our products.

The Company's reputation is the foundation of our relationships with physicians, patients and other customers. If we are unable to effectively manage real or perceived issues, which could negatively impact sentiments toward the Company, our business could suffer. Pharmaceuticals and medical devices are perceived to be dangerous products and our customers may have a number of concerns about the safety of our products whether or not such concerns have a basis in generally accepted science or peer-reviewed scientific research. These concerns may be increased by negative publicity, even if the publicity is inaccurate. In addition, government investigations related to the use of our products, but not the efficacy of the products themselves, may cause reputational harm to the Company. Negative publicity could also result in an increased number of product liability claims, whether or not these claims have a basis in scientific fact.

We are also subject to adverse event reporting regulations that require us to report to the FDA or similar bodies in other countries if our products are associated with a death or serious injury, even if there is no available evidence of a causal relationship between the adverse event and the product. Such reports may be publicly released by the FDA and other authorities. Furthermore, any adverse publicity associated with adverse events for our products, and related post-marketing actions, could cause consumers to seek alternatives to our products, and thereby cause our sales to decline, even if our products are ultimately determined not to have been the primary cause of the adverse event.

Pharmaceutical products can develop unexpected safety or efficacy concerns, which could have a material adverse effect on our business.

Pharmaceutical products receive regulatory approval based on data obtained in controlled clinical trials of limited duration. After approval, the products are used for longer periods of time by much larger numbers of patients; we and others (including regulatory agencies and private payers) collect extensive information on the efficacy and safety of our marketed products by continuously monitoring the use of our products in the marketplace. In addition, we or others may conduct post-marketing clinical studies on efficacy and safety of our marketed products. New safety or efficacy data from market surveillance, post-marketing clinical studies or general use may result in product label changes, product recalls, withdrawals, or declining sales, as well as product liability, consumer fraud and/or other claims, including potential civil or criminal governmental actions.

Product labeling changes for our marketed products could result in a negative impact on revenues.

We or regulatory authorities may need to change the labeling for any pharmaceutical product, including after a product has been marketed for several years. These changes are often the result of additional data from post-marketing studies, head-to-head trials, adverse events reports, studies that identify biomarkers (objective characteristics that can indicate a particular response to a product or therapy) or other studies or post-marketing experience that produce important additional information about a product. New information added to a product's label can affect its risk-benefit profile, leading to potential recalls, withdrawals, or declining revenue, as well as product liability claims. Sometimes additional information from these studies identifies a portion of the patient population that may be non-responsive to a medicine or would be at higher risk of adverse reactions and labeling changes based on such studies may limit the patient population. The studies providing such additional information may be sponsored by us, but they could also be sponsored by competitors, insurance companies, government institutions, managed care organizations, scientists, investigators, or other interested parties. While additional safety and efficacy

information from such studies assist us and healthcare providers in identifying the best patient population for each product, it can also negatively impact our revenues due to inventory returns and a more limited patient population going forward. Additionally, certain study results, especially from head-to-head trials, could affect a product's formulary listing, which could also adversely affect our revenues.

We are dependent on our collaborative agreements for the development of products and business development, which exposes us to the risk of reliance on the viability of third parties.

In conducting our research and development activities, we currently rely, and will in the future rely, on collaborative agreements with third parties such as manufacturers, contract research organizations, commercial partners, universities, governmental agencies and not-for-profit organizations for both strategic and financial resources. The loss of, or failure to perform by us or our partners under, any applicable agreements or arrangements, or our failure to secure additional agreements for other products in development, would substantially disrupt or delay our research and development and commercialization activities. Any such loss would likely increase our expenses and materially harm our business, financial condition and results of operation.

We extensively outsource our clinical trial activities and usually perform only a small portion of the start-up activities in-house.

We rely on independent third-party contract research organizations (CROs) to perform most of our clinical studies, including document preparation, site identification, screening and preparation, pre-study visits, training, program management and bioanalytical analysis. Many important aspects of the services performed for us by the CROs are out of our direct control. If there is any dispute or disruption in our relationship with our CROs, our clinical trials may be delayed. Moreover, in our regulatory submissions, we rely on the quality and validity of the clinical work performed by third-party CROs. If any of our CROs' processes, methodologies or results were determined to be invalid or inadequate, our own clinical data and results and related regulatory approvals could be adversely impacted.

Reliance on third-party relationships and outsourcing arrangements could adversely affect our business.

We utilize third parties, including suppliers, alliances with other pharmaceutical and biotechnology companies, and third-party service providers, for selected aspects of product development, the manufacture and commercialization of certain products, support for information technology systems, and certain financial transactional processes. For example, we may outsource the day-to-day management and oversight of our clinical trials to contract research organizations and the manufacture of certain of our products. Outsourcing these functions involves the risk that the third parties may not perform to our standards or legal requirements, may not produce reliable results, may not perform in a timely manner, may not maintain the confidentiality of our proprietary information, or may fail to perform at all. Failure of these third parties to meet their contractual, regulatory, confidentiality, or other obligations to us could have a material adverse effect on our business.

Product liability claims could harm our business.

The development, manufacture, testing, marketing and sale of pharmaceutical products are associated with significant risks of product liability claims. Side effects or adverse events known or reported to be associated with, or manufacturing defects in, the products sold by us could exacerbate a patient's condition, or could result in serious injury or impairments or even death. This could result in product liability. Some of our products, including Eucontra, will have boxed warnings in their labels. Product liability claims may be brought by individuals seeking relief for

themselves, or by groups seeking to represent a class of injured patients. Further, third party payers, either individually or as a putative class, may bring actions seeking to recover monies spent on one of our products. As sales of our products increase, the risk that product liability claims will be made against us increases. The risk of product liability claims may also increase if a company receives a warning letter from a regulatory agency. We cannot predict the frequency, outcome or cost to defend any such claims.

Product liability insurance coverage is expensive, can be difficult to obtain and may not be available to us in the future on acceptable terms, or at all. Our product liability insurance may not cover all of the future liabilities we might incur in connection with the development, manufacture or sale of our products. In addition, we may not continue to be able to obtain insurance on satisfactory terms or in adequate amounts. A successful claim or claims brought against us in excess of available insurance coverage could subject us to significant liabilities and could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Such claims whether meritorious or not could also harm our reputation and the reputation of our products, adversely affecting our ability to market our products successfully. In addition, defending a product liability lawsuit is expensive and can divert the attention of key employees from operating our business.

In addition, product liability claims could result in an investigation of the safety or efficacy of our products, our manufacturing processes and facilities, or our marketing programs conducted by the FDA, the EMA, or the competent authorities of the EU member states. Such investigations could also potentially lead to a recall of our products or more serious enforcement actions, limitations on the indications for which they may be used, or suspension, variation, or withdrawal of approval, any of which would adversely affect our business.

If we are unable to negotiate and maintain satisfactory arrangements with group purchasing organizations with respect to the purchase of our products, our business could be adversely affected.

Our ability to sell our products to hospitals in the United States depends in part on our relationships with group purchasing organizations, or GPOs. Many existing and potential customers for our products become members of GPOs. GPOs negotiate pricing arrangements and contracts, sometimes on an exclusive basis, with medical supply manufacturers and distributors. These negotiated prices are then made available to a GPO's affiliated hospitals and other members. If we are not one of the providers selected by a GPO, affiliated hospitals and other members may be less likely to purchase our products, and if the GPO has negotiated a strict sole source, market share compliance or bundling contract for another manufacturer's products, we may be precluded from making sales to members of the GPO for the duration of the contractual arrangement. Our failure to renew contracts with GPOs may cause us to lose market share and could have a material adverse effect on our sales, financial condition and results of operations. We cannot assure you that we will be able to renew these contracts at the current or substantially similar terms. If we are unable to keep our relationships and develop new relationships with GPOs, our competitive position may suffer.

We are subject to complex government healthcare legislation and reimbursement programs, as well as other cost-containment pressures.

Many of our products will be purchased or reimbursed by federal and state government authorities, private health insurers and other organizations, including health maintenance and managed care organizations. These third-party payers increasingly challenge pharmaceutical and medical device product pricing, which could result in lower reimbursement rates and a reduction in demand for our products.

In addition, legislative and regulatory proposals and enactments to reform healthcare insurance programs could significantly influence the manner in which pharmaceutical products, biologic products and medical devices are prescribed and purchased. Individual states have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and to encourage importation from other countries and bulk purchasing. Furthermore, regional healthcare 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 healthcare programs. Any legally mandated price controls or utilization of bidding procedures could negatively and materially impact our revenues, results of operations and financial condition.

Increased pricing pressure and other restrictions in the U.S. and abroad from managed care organizations, institutional Investors, and government agencies and programs, among others, could negatively affect our revenues and profit margins.

Our products continue to be subject to increasing pressures from market access, pricing and rebates and other restrictions in the U.S., the EU and other regions around the world, including from (i) rules and practices of managed care organizations and institutional and governmental Investors; (ii) judicial decisions and governmental laws and regulations for Medicare, Medicaid and U.S. healthcare reform, including the 2010 Patient Protection and Affordable Care Act; (iii) the potential impact of pharmaceutical reimbursement, Medicare Part D Formularies and product pricing in general; (iv) delays in gaining reimbursement; (v) government price erosion mechanisms across Europe and in other countries, resulting in deflation for pharmaceutical product pricing; (vi) collection delays in government-funded public hospitals outside the U.S. (vii) the impact on pricing from parallel trade across borders; (viii) other developments in technology and/or industry practices that could impact the reimbursement policies and practices of third-party payers; and (ix) limited or blocked market access due to real or perceived differences in value propositions for our products compared to competing products.

The illegal importation of counterfeit products and pharmaceutical and medical device products from countries where government price controls or other market dynamics result in lower prices may adversely affect our sales and profitability in the U.S. and other countries in which we operate.

Foreign imports are illegal under current U.S. law, with the sole exception of limited quantities of prescription drugs imported for personal use. However, the volume of illegal imports continues to rise as the ability of patients and other customers to obtain these lower priced imports has grown significantly. In addition, U.S. policy makers may expand consumers' ability to import lower priced versions of our products and competing products from Canada, where there are government price controls. Any future legislation or regulations that increase consumer access to lower priced medicines from outside the U.S. may lower the prices we receive for our products, which could adversely impact our revenues.

BUSINESS

Description of the Business

Hera Health Solutions is a pharmaceutical device company that specializes in the development and commercialization of long acting treatments through proprietary bio-erodible implants.

Business Plan

Hera Health intends to sell its first product, the contraceptive biodegradable implant Eucontra, to OB/GYN practices as well as family planning clinics in the U.S. market. Internationally, the Company will seek to sell to nonprofit organizations and large-scale Non-Governmental Organizations (NGOs) that distribute contraceptives to countries with a limited access to healthcare. It also intends to price Eucontra at \$800 per device, which the Company believes is competitive with its alternative, Nexplanon. The executive team estimates a 98.5% gross margin for retail sales but intends to heavily subsidize Eucontra for bulk distribution to humanitarian partners.

Hera Health aims to spread awareness for Eucontra mainly through partnerships and sponsorships within the OB/GYN and family planning spaces, as well as with global humanitarian organizations and healthcare distributors who focus on areas related to family planning and women's health. If the product is approved for use by the FDA, the Company also plans to launch an extensive commercial marketing campaign involving sales representatives and media advertisement. The Company's domestic growth plan also heavily involves broadening professionals' knowledge of its technology through trade shows and conferences.

Nationally, the Company has mapped out potential conferences in the U.S. to attend with the goal of further networking with key opinion leaders on a national level in the hopes of gaining additional endorsements for its technology. The executive team will seek to keep these connections engaged as the Company continues to develop Eucontra and fulfill the necessary regulatory requirements for FDA approval.

History of the Business

The Company was incorporated on May 22, 2017 under the laws of Delaware. The idea for Hera Health started as a biomedical engineering capstone project at Georgia Tech, where Bioengineering students were given a task to locate and remove lost implants in the arm. Along the way, the Hera Health team developed a technology that would eliminate the problem from ever occurring in the first place. Now, the Company's goal is to provide a drug delivery implant that could change the way people take regimented medication all over the world.

In May 2018, Hera Health participated in the ZeroTo510 summer accelerator. The program is a 100-day intensive, hands-on educational program that speeds up the development of high-tech, high-growth startup companies. The accelerator focused on four industries including home services, medical device, supply chain and logistics, and Agricultural technology and innovation.

The Company's Products and/or Services

Product / Service	Description	Potential Market
Eucontra	A biodegradable, long-acting contraceptive arm implant	OB/GYNs with private practices, family planning organizations, and/or midsize to large non-profit organizations.

We are constantly researching and developing new formulations of our products to move into other long acting pharmaceutical markets. The total addressable market for long acting medications is \$300 billion.¹ Proceeds from this raise will be used to help the Company continue research and development and undergo the Food and Drug Administration approval process.

In the U.S., we intend to sell and distribute our product as a pharmaceutical device aligned with other contraceptive products. Internationally, we intend to sell the product through strategic non-profit organization partnerships.

Competition

The Company's primary competitors are Merck, the Bayer Group, Allergan, and Cooper Surgical. Similar competitive devices include Nexplanon, Mirena, Skyla, Liletta, and ParaGuard.

We believe our product is best suited to directly address the removal issues associated with the contraceptive arm implant. Other forms of available long acting contraceptive options on the market include Nexplanon, IUDs, and the birth control pill. We believe many of these other options are either more invasive, less effective, require a strict pill taking regimen, and/or are not discreet. We intend for the pricing of our product to be very competitive compared to the other options available in the market. Moreover, our Company's long-acting drug delivery platform aims to move into other generic medications in an industry valued at an estimated \$300 billion industry.²

Customer Base

We intended to market our product to OB/GYNs with private practices, family planning organizations, and/or midsize to large non-profit organizations.

Intellectual Property

Patents

Application or Registration #	Title	Description	File Date	Grant Date	Country
US20190008 792A1	Bio-erodible Drug Delivery Implants	Biodegradable drug delivery devices including one or more active agents, and related methods. The devices are useful for administering a wide variety of	July 8, 2017	TBD	US

¹ <https://www.marketwatch.com/press-release/injectable-drug-delivery-market-2018-in-depth-analysis-by-types-key-players-applications-growth-factors-trend-forecast-2025-2018-10-30>

² <https://www.marketwatch.com/press-release/injectable-drug-delivery-market-2018-in-depth-analysis-by-types-key-players-applications-growth-factors-trend-forecast-2025-2018-10-30>

		agents over prolonged periods of time.			
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Governmental/Regulatory Approval and Compliance

Our business has been and will continue to be subject to the Food and Drug Administration and various other U.S. laws and regulations. Failure to comply with these laws and regulations could subject us to administrative and legal proceedings and actions by these various governmental bodies.

Litigation

There are no existing legal suits pending, or to the Company's knowledge, threatened, against the Company.

Other

The Company's principal address is 11141 Wellshire Ln., Frisco, TX 75035

The Company has the following additional addresses: 88 Union Ave. Suite 200 Memphis, TN 38103

The Company conducts business in Tennessee.

DIRECTORS, OFFICERS AND EMPLOYEES

Directors

The directors or managers of the Company are listed below along with all positions and offices held at the Company and their principal occupation and employment responsibilities for the past three (3) years and their educational background and qualifications.

Name

[Idicula Mathew – CEO] [June 2016 – Present]

Officers

The officers of the Company are listed below along with all positions and offices held at the Company and their principal occupation and employment responsibilities for the past three (3) years and their educational background and qualifications.

Name

Idicula Mathew

All positions and offices held with the Company and date such position(s) was held with start and ending dates

Officer, June 13, 2017 to Present

President, Secretary and CEO, June 2017 to Present

Principal occupation and employment responsibilities during at least the last three (3) years with start and ending dates

Idicula is currently the President and CEO of Hera Health solutions. He has been CEO since the Company's inception, and his responsibilities include providing vision, leading business development, filling for intellectual property, and the overall commercialization of the Company's product. He has a background in product development with a concentration in biotechnology research, and he has prior startup experience.

Education

Idicula obtained a Bachelor of Science Degree in Bioengineering and Biomedical Engineering from the Georgia Institute of Technology.

Name

Garrett Whitfield

All positions and offices held with the Company and date such position(s) was held with start and ending dates

Officer, June 2017 to Present

Vice President and COO, June 13, 2017, to Present

Principal occupation and employment responsibilities during at least the last three (3) years with start and ending dates

Garret is currently the Vice President and COO of Hera Health solutions. He has worked together with Idicula since Eucontra's idea creation phase in early 2016. His responsibilities include leading the Company's internal processes, managing human resources, and overseeing quality management.

Garrett co-founded Hera Health Solutions and has a background in prototyping and manufacturing medical device technology.

Education

Garret obtained a bachelor's degree in Biomedical Engineering and Leadership Studies from the Georgia Institute of Technology.

Indemnification

Indemnification is authorized by the Company to directors, officers or controlling persons acting in their professional capacity pursuant to Delaware law. Indemnification includes expenses such as attorney's fees and, in certain circumstances, judgments, fines and settlement amounts actually paid or incurred in connection with actual or threatened actions, suits or proceedings involving such person, except in certain circumstances where a person is adjudged to be guilty of gross negligence or willful misconduct, unless a court of competent jurisdiction determines that such indemnification is fair and reasonable under the circumstances.

Employees

The Company currently has four employees in Tennessee.

CAPITALIZATION AND OWNERSHIP

Capitalization

The Company has issued the following outstanding Securities:

Type of Security	Common Stock
Amount Outstanding	711,000
Voting Rights	Each share of common stock is entitled to one vote for the election of directors and other matters upon which the stockholders of the Company are entitled to vote.
Anti-Dilution Rights	No anti-dilution, put or call rights
How this Security may limit, dilute or qualify the Notes/Bonds issued pursuant to Regulation CF	N/A

Type of Security	Series Seed Preferred Stock
Amount Outstanding	176,934
Voting Rights	Each share of common stock is entitled to one vote for the election of directors and other matters upon which the stockholders of the Company are entitled to vote.
Anti-Dilution Rights	No anti-dilution, put or call rights
How this Security may limit, dilute or qualify the Notes/Bonds issued pursuant to Regulation CF	N/A

Ownership

A majority of the Company is owned by two founders. Those people are Idicula Mathew and Garrett Whitfield.

Below the beneficial owners of 20% percent or more of the Company's outstanding voting equity securities, calculated on the basis of voting power, are listed along with the amount they own.

Name	Percentage Owned
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Founders: Idicula Mathew & Garrett Whitfield	65%
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FINANCIAL INFORMATION

Please see the financial information listed on the cover page of this Form C-AR and attached hereto in addition to the following information. Financial statements are attached hereto as Exhibit A.

Recent Tax Return Information

Total Income	Taxable Income	Total Tax
-\$203,650	0	0

Liquidity and Capital Resources

In July 2019 the Company started an offering pursuant to Regulation CF, which was closed in August 2019 raising \$106,995.

The Company has the following sources of capital in addition to the proceeds from the Regulation CF Offering:

1. Innova Memphis- VC lead investor for Series Seed round
2. BioExel- Series Seed Investor
3. Various investors – Accredited Series Seed Investors

Capital Expenditures and Other Obligations

The Company does not intend to make any material capital expenditures in the near future.

Material Changes and Other Information

Trends and Uncertainties

The financial statements are an important part of this Form C-AR and should be reviewed in their entirety. The financial statements of the Company are attached hereto as Exhibit A.

Restrictions on Transfer

Any Securities sold pursuant to Regulation CF being offered may not be transferred by any Investor of such Securities during the one-year holding period beginning when the Securities were

issued, unless such Securities were transferred: 1) to the Company, 2) to an accredited investor, as defined by Rule 501(d) of Regulation D of the Securities Act of 1933, as amended, 3) as part of an Offering registered with the SEC or 4) to a member of the family of the Investor or the equivalent, to a trust controlled by the Investor, to a trust created for the benefit of a family member of the Investor or the equivalent, or in connection with the death or divorce of the Investor or other similar circumstances. "Member of the family" as used herein means a child, stepchild, grandchild, parent, stepparent, grandparent, spouse or spousal equivalent, sibling, mother/father/daughter/son/sister/brother-in-law, and includes adoptive relationships. Remember that although you may legally be able to transfer the Securities, you may not be able to find another party willing to purchase them.

TRANSACTIONS WITH RELATED PERSONS AND CONFLICTS OF INTEREST

Related Person Transactions

From time to time the Company may engage in transactions with related persons. Related persons are defined as any director or officer of the Company; any person who is the beneficial owner of 10 percent or more of the Company's outstanding voting equity securities, calculated on the basis of voting power; any promoter of the Company; any immediate family member of any of the foregoing persons or an entity controlled by any such person or persons.

The Company has conducted the following transactions with related persons:

On May 5, 2018, the Company entered into loan agreements with Idicula Mathew in the principal amount of \$4,184 with no interest. The loan does not bare a prepayment penalty. The Company has repaid \$3,488 of the outstanding principal. Pursuant to the terms of the loan, the Company promises to repay the balance of the loan on or before the next fundraising event.

Bad Actor Disclosure

The Company is not subject to any Bad Actor Disqualifications under any relevant U.S. securities laws.

SIGNATURE

Pursuant to the requirements of Sections 4(a)(6) and 4A of the Securities Act of 1933 and Regulation Crowdfunding (§ 227.100 et seq.), the issuer certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form C-AR and has duly caused this Form to be signed on its behalf by the duly authorized undersigned.

The issuer also certifies that the attached financial statements are true and complete in all material respects.



(Signature)

Idicula Mathew

(Name)

CEO

(Title)

Pursuant to the requirements of Sections 4(a)(6) and 4A of the Securities Act of 1933 and Regulation Crowdfunding (§ 227.100 et seq.), this Form C-AR has been signed by the following persons in the capacities and on the dates indicated.



(Signature)

Idicula Mathew

(Name)

President & Director

(Title)

4/28/2021

(Date)

EXHIBITS

Exhibit A Financial Statements

EXHIBIT A
Financial Statements

Hera Health Solutions Inc.
Consolidated Balance Sheets as of
December 31, 2020

<u>Assets</u>	<u>2020</u>
Cash and Cash Equivalents	\$670,295
Receipts Receivable	\$0.00
Prepaid Expenses	\$0.00
Total Current Assets	\$670,295
 Total Long-Term Assets	 \$0.00
 Intangible Assets	 \$3,455,000
Total Assets	\$4,125,295
 <u>Liabilities and Shareholders' Equity</u>	
<u>Liabilities</u>	
Founders Loan Account	\$81,346
Accounts Payable	\$48,245
Total Current Liabilities	\$129,591
 Total Liabilities	 \$129,591
 <u>Shareholders' Equity</u>	
Authorized Stock 1,090,000 @ \$5	
Issued Stock 887,934 @ \$5	\$4,439,670
Retained Earnings	(\$443,966)
 Total Liabilities and Shareholders' Equity	 \$4,125,295

HERA HEALTH SOLUTIONS INC.,
Consolidated Statements of Income
Years Ended Dec 31st, 2020

	<u>2020</u>
Income from Operations	\$0
Gross Profit	\$0
 Income from Non-Operating Activities	
SBA PPP	\$16,600
Interest	\$3,834
 Operating Expenses	
Office/Lab Rent	(\$20,400)
Manufacturing/ Product Testing	(\$7,118)
Accelerator Programming	(\$0.00)
R&D / Regulatory Preparation	(\$56,575)
Utilities	(\$3,360)
Travel	(\$2,476)
Salary	(\$88,444)
Legal Fee	(\$2,596)
IP/Patent	(\$42,038)
Fees and Advertising	(\$678)
Conference	(\$399)
Total Other Expenses	(\$224,084)
 Net Income:	 (\$203,650)

