June 15, 2020

FORM C-AR

ZENII, LLC

This Form C-AR (including the cover page and all exhibits attached hereto, the "Form C-AR") is being furnished by ZENII, LLC, d/b/a Intrommune Therapeutics, a New York Limited Liability Company (the "Company" or "Intrommune," 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.intrommune.com no later than 120 days after the end of each fiscal year covered by the report. The Company may terminate its reporting 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 three 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 June 15, 2020.

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.

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.

ZENII, LLC, d/b/a Intrommune Therapeutics (the "Company" or "Intrommune") is a New York limited Liability Company, formed on December 31, 2013.

The Company is located at 20 West 125th Street, New York, NY 10027.

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

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

The Business

The Company is a New York City-based biotechnology company dedicated to simplifying allergy immunotherapy. Intrommune's core technology enables immunotherapeutic agents to be delivered in a specially formulated toothpaste designed to incorporate and stabilize allergenic proteins, representing a new therapeutic approach for the treatment of peanut and other food allergies. Conducting allergy immunotherapy via teeth brushing is referred to as oral mucosal immunotherapy (OMIT). OMIT delivers allergenic proteins to the areas of the oral cavity, potentially driving the immune system toward tolerance without ingestion of the allergen. OMIT may address a significant health care need in the industrialized world, where the spread of food allergies has been characterized as an "epidemic."

RISK FACTORS

RISKS RELATED TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

Our short operating history may make it difficult for you to evaluate the success of our business to date and our future viability.

Start-up investing is risky. Investing in early-stage companies is very risky, highly speculative, and should not be made by anyone who cannot afford to lose their entire investment. We are a development stage biopharmaceutical company with a very limited operating history. Developing and commercializing our current product candidate and any future product candidates will require significant pre-clinical and clinical testing, as well as regulatory approvals for commercialization and marketing before we will be allowed to begin any significant product sales. In addition, commercialization of our product candidates likely would require us to establish a sales and marketing organization and contractual relationships to enable product manufacturing and other related activities. Consequently, it may be difficult for you to make any predictions about our future success or viability.

We have incurred significant losses since inception. We expect to continue to incur losses for the foreseeable future and may never achieve or maintain profitability.

We have incurred losses in each year since inception and expect to continue to experience losses over the next several years. As of December 31, 2019, we had an accumulated deficit of approximately $970,274.

Our principal intellectual property is licensed from an affiliated company, Allovate, LLC, as described under "Related Party Transactions." The license agreement with Allovate, which became effective on June 29, 2018, provides for license payments on the achievement of specified milestones, including milestone payments before regulatory approval is received to sell any licensed product, and the assumption of $500,000 of indebtedness, plus interest, incurred by Allovate in acquiring some of the licensed patent rights.

We expect to continue to incur significant operating expenses and anticipate that our expenses and losses will increase in the foreseeable future as we seek to:

• gain regulatory approvals for our products that successfully complete clinical trials;

• maintain, expand and protect our intellectual property portfolio;

• seek to commercialize our products;

• hire additional clinical, regulatory, quality control, scientific and management personnel; and

• add operational, financial, accounting, facilities engineering, manufacturing and information systems personnel, consistent with expanding our operations.

To become and remain profitable, we must succeed in developing and eventually commercializing products with significant market potential. This will require us to be successful in a range of challenging activities, including successfully completing preclinical testing and clinical trials of our products, obtaining regulatory approval for our products and manufacturing, marketing and selling our products. We are only in the preliminary stages of many of these activities. We may never succeed in these activities and may never generate revenues that are significant or large enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the price of our equity securities and could impair our ability to raise capital, expand our business or continue our operations.

We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We are a pre-clinical stage company focused on the development of an oral mucosal immunotherapy platform for the treatment of food allergies. We anticipate that our product candidates will not be commercially available for several years, if at all.

We expect that our research and development expenses will continue to increase in connection with our ongoing activities, particularly as we commence clinical development for our products. We will need to raise additional funds to complete our planned clinical trial programs. If the early stage clinical trials of our products produce positive results, we may need to enter into one or more collaboration agreements with one or more third parties to conduct and fund larger, later-stage clinical trials, including potential pivotal Phase 3 clinical trials. If we are not able to enter into collaboration agreements on terms that are acceptable to us, we will need to raise additional capital to fund these trials or delay or abandon the trials. In addition, we expect to incur significant commercialization expenses for product sales and marketing. Accordingly, we expect that we will need substantial additional funding and may be unable to raise capital when needed or on attractive terms, which would force us to delay, reduce or eliminate our research and development programs or commercialization efforts.

Our future capital requirements will depend on many factors, including:

• the scope, progress and results of our research and preclinical development programs;

• the scope, progress, results, costs, timing and outcomes of the clinical trials of our products;

• the timing of entering into, and the terms of, one or more collaboration agreements with one or more third parties for our products;

• the timing of and the costs involved in obtaining regulatory approvals for our products;

• the costs of operating, expanding and enhancing manufacturing facilities and capabilities to support our clinical activities and our commercialization activities;

• the costs of maintaining, expanding and protecting our intellectual property portfolio, including

potential litigation costs and liabilities;

• revenues received from sales of our products; and

• the costs of additional general and administrative personnel, including accounting and finance, legal and human resources employees.

As a result of these and other factors, we expect that we will seek additional funding in the future. We would likely seek such funding through debt or equity financings or some combination of the two. We will also likely seek funding through collaborative arrangements if we determine them to be necessary or appropriate. Additional funding may not be available on acceptable terms, or at all. If we obtain capital through collaborative arrangements, these arrangements could require us to relinquish rights to our technology or products and could result in us receiving only a portion of the revenues associated with the partnered product. If we raise capital through the sale of equity, or securities convertible into equity, it would result in dilution to our then existing equity holders. If we raise additional capital through the incurrence of indebtedness, we would likely become subject to covenants restricting our business activities, and holders of debt instruments would have rights and privileges senior to those of our equity investors. In addition, servicing the interest and principal repayment obligations under debt facilities could divert funds that would otherwise be available to support research and development, clinical or commercialization activities.

If we are unable to obtain adequate financing on a timely basis in the future, we would likely be required to delay, reduce or eliminate one or more product development programs.

If we fail to successfully manage our growth, our business could be adversely affected.

We anticipate increasing the scale of our operations as we develop our products. If we are unable to manage our growth effectively, our operations and financial condition could be adversely affected. The management of our growth will depend, among other things, upon our ability to develop and improve our operational, financial and management controls, reporting systems and procedures. Furthermore, we may have to make investments in and hire and train additional personnel for our operations, which would result in additional burdens on our systems and resources and require additional capital expenditures.

The COVID-19 pandemic may materially and adversely affect our ability to raise capital and may have serious and negative effects on our business and operations in general.

The COVID-19 pandemic is severely disrupting global financial markets, which may reduce our ability to access capital and negatively impact our short-term and long-term liquidity. The COVID-19 pandemic may affect our operations and those of third parties on which we rely, including by causing disruptions in the supply of materials we need to develop our product candidates and the conduct of any future clinical trials. In addition, the COVID-19 pandemic may affect the operations of the United States Food and Drug Administration ("FDA") and other health authorities, which could result in delays of reviews and approvals, including with respect to our product candidates. The COVID-19 pandemic may make it more difficult for us to enroll patients in clinical trials as patients may avoid or may not be able to travel to healthcare facilities, and healthcare facilities and personnel may be required to focus their resources on treatment of COVID-19 patients, and may not be available for clinical trial services. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, financing or other activities or on healthcare systems or the global economy as a whole. However, these effects could have a material impact on our liquidity, capital resources, operations and business and those of the third parties on which we rely.

RISKS RELATED TO DEVELOPMENT OF OUR PRODUCTS

Our product development programs will be based on novel technologies and are inherently risky.

We will be subject to the risks of failure inherent in the development of products based on new technologies. The novel nature of our oral mucosal immunotherapy platform for the treatment of food allergies creates significant challenges with respect to product development and optimization, manufacturing, government regulation and approval, third-party reimbursement and market acceptance. There are currently no oral immunotherapy products approved by the FDA for the treatment of food allergies, increasing the uncertainty of any future regulatory approval of our products. The FDA may not approve our products or may approve them with certain restrictions that may limit our ability to market our products, and our products may not be successfully commercialized, if at all.

Our clinical trials may not be successful.

We intend to conduct clinical studies. Preclinical and clinical testing is expensive, difficult to design and implement and can take many years to complete. A failure of one or more of our preclinical studies or clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent our ability to obtain regulatory approval or commercialize our products, including:

• our preclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials or we may abandon projects that we currently expect to be promising;

• regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;

• enrollment in clinical trials may take longer than expected or the clinical trials as designed may not allow for sufficient patient accrual to complete enrollment of the trial;

• conditions imposed by the FDA or any non-US regulatory authority regarding the scope or design of our clinical trials may require us to submit information to regulatory authorities, ethics committees or others for review and approval;

• the number of patients required for our clinical trials may be larger than anticipated or participants may drop out of clinical trials at a higher rate than anticipated;

• third party contractors or clinical investigators may fail to comply with regulatory requirements or fail to meet their contractual obligations in a timely manner;

• we may have to suspend or terminate clinical trials if we, regulators or institutional review boards determine that the participants are being exposed to unacceptable health risks;

• we may not be able to demonstrate that our products provide an advantage over current standard of care or future competitive therapies in development;

• regulators or institutional review boards may require us to hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;

• the cost of clinical trials may be greater than anticipated;

• the supply or quality of the materials necessary to conduct clinical trials may be insufficient or inadequate or we may not be able to reach agreements on acceptable terms with prospective clinical research organizations; and

• the effects of our formulations may not be the desired effects or may include undesirable side effects.

We have limited experience in conducting and managing the preclinical development activities and clinical trials necessary to obtain regulatory approvals, including approval by the FDA. Our limited experience might prevent us from successfully designing or implementing a clinical trial. We have limited experience in conducting and managing the application process necessary to obtain regulatory approvals and might not be able to demonstrate that our products meet the appropriate standards for regulatory approval. If we are not successful in conducting and managing our preclinical development activities or clinical trials or obtaining regulatory approvals, we might not be able to commercialize our products, or might be significantly delayed in doing so, which will materially harm our business.

If we are not able to retain qualified personnel, we may fail to develop our technologies and product candidates.

Our future success depends to a significant extent on the skills, experience and efforts of the principal members of our management personnel. These members include Michael Nelson and Erick Berglund, PhD. The loss of any one of these people could harm our business and might significantly delay or prevent the achievement of research, development or business objectives. Competition for personnel is intense. We may find it difficult to retain qualified personnel with the appropriate management, scientific and business skills necessary for the success of our business. We may be unable to retain our current personnel or attract or integrate other qualified personnel in the future.

We may not be able to secure and maintain relationships with research institutions and clinical investigators that are capable of conducting and have access to necessary patient populations for the conduct our clinical trials.

We will rely on research institutions and clinical investigators to conduct our clinical trials. Our reliance upon research institutions, including hospitals and clinics, provides us with less control over the timing and cost of clinical trials and the ability to recruit subjects. If we are unable to reach agreement with suitable research institutions and clinical investigators on acceptable terms, or if any resulting agreement is terminated because, for example, the research institution and/or clinical investigators lose their licenses or permits necessary to conduct our clinical trials, we may be unable to quickly replace the research institution and/or clinical investigator with another qualified research institution and/or clinical investigator on acceptable terms. We may not be able to secure and maintain agreement with suitable research institutions to conduct our clinical trials.

Developments by competitors may render our products or technologies obsolete or non-competitive.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our oral mucosal immunotherapy platform for the treatment of food allergies has to compete with existing treatments. In addition, companies are pursuing the development of pharmaceuticals that target the same conditions that we are targeting. We face competition from pharmaceutical and biotechnology companies in the United States and abroad. In addition, companies pursuing different but related fields represent substantial competition. Many of these organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, longer product development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel and parties for acquisitions, joint ventures or other collaborations.

Our products may not gain market acceptance, which would have a negative impact on our sales.

Our products may not gain market acceptance by physicians, patients, third-party payors and others in the medical community. If the products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of our products will depend on a number of factors, including:

• The prevalence and severity of any side effects, including any limitations or warnings contained in approved labeling;

• The efficacy and potential advantages over alternative treatments or avoidance, such as oral immunotherapy, epicutaneous immunotherapy and allergy medications;

• Product pricing;

• The willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

• The strength of marketing and distribution support and timing of market introduction of competitive products;

• Publicity concerning us or competing products and treatments; and

• Sufficient third-party insurance coverage or reimbursement.

Our efforts to educate the medical community and third-party payors on the benefits of our products may require significant resources and may never be successful. Such efforts to educate the marketplace may require more resources than are required by the conventional technologies marketed by our competitors.

We may not be able to develop the collaborative relationships that we may need to develop and market our products.

We will seek to pursue partnership opportunities, licensing relationships and other collaborative relationships that will expand and enhance our product development plans, including, among other things, partners that would provide us with expertise in stabilizing allergen formulations and permit our long-term access to validated allergen sources. Reliance on partnerships, licenses and collaborative relationships poses a number of risks, however, including the following:

• We may face significant competition in seeking appropriate collaborators and licensees;

• Collaboration and licensing arrangements are complex and time consuming to negotiate, document and implement;

• We may not be successful in our efforts to establish and implement collaborations, licenses or other alternative arrangements that we might pursue on favorable terms;

• We may not be able to effectively control whether our partners will devote sufficient resources to our programs or products;

• Disputes may arise in the future with respect to the ownership of rights to technology developed with, licensed to or licensed from partners;

• Disagreements with partners and licensees are difficult to resolve and could result in loss of intellectual property rights, delay or terminate the research, development or commercialization of

product candidates or result in litigation or arbitration;

• Contracts with partners and licenses may fail to provide sufficient protection of our intellectual property; and

• We may have difficulty enforcing the contracts if one of these partners or licensees fails to perform.

A great deal of uncertainty exists regarding the success of any collaborative efforts. Failure of these efforts could delay, impair or prevent the development and commercialization of our products and adversely affect our business, financial condition, results of operations and prospects.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

The manufacture and sale of human therapeutic products involves an inherent risk of product liability claims and associated adverse publicity. We face product liability exposure related to the testing of our product candidates in human clinical trials, and claims could be brought against us if use or misuse of one of our product candidates causes, or merely appears to have caused, personal injury or death.

We intend to obtain product liability insurance for our products and development program, but we do not know if we will be able to continue to obtain product liability insurance on acceptable terms or with adequate coverage against potential liabilities in the future. This type of insurance is expensive and may not be available on acceptable terms. If we are unable to maintain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims, we may be unable to commercialize our products. A successful product liability claim brought against us in excess of its insurance coverage, if any, may require payment of substantial amounts and have a material adverse effect on our business, financial condition, results of operations or future prospects.

If we are unable to protect our intellectual property, our competitiveness and business prospects may be materially damaged.

Our success will depend in part on our ability to protect proprietary technology and to obtain patent protection for our products, prevent third parties from infringing on our patents and refrain from infringing on the patents of others, both domestically and internationally.

We believe that we have access to the material intellectual property that we need to develop and commercialize our product candidates as currently contemplated, but in the future we may need access to additional intellectual property if our plans change or unforeseen circumstances arise. Any arrangement with respect to such intellectual property rights may result in dilution to our equity holders and additional debt and royalty obligations and other payment obligations for us.

In addition, the patent situation in the field of biotechnology and pharmaceuticals generally is highly uncertain and involves complex legal, technical, scientific and factual questions. We intend to actively pursue patent protection for products resulting from our research and development activities that have significant potential commercial value. We may not be able to obtain issued patents relating to our technology or products.

Even if issued, patents issued to us or our licensors may be challenged, narrowed, invalidated, held to be unenforceable or circumvented, which could limit our ability to stop competitors from marketing similar products or reduce the term of patent protection we may have for our products.

There can be no assurance that any patents obtained will afford us with adequate protection or provide us with any meaningful competitive advantages against these competitors.

Changes in either patent laws or in interpretations of patent laws in the US and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. In addition, any patents we procure may require cooperation with companies holding related patents and we may have difficulty forming a successful relationship with such other companies.

Third parties may claim that we are infringing upon or have misappropriated their proprietary rights. We can give no assurances as to whether any issued patents, or patents that may later issue to third parties, would affect our contemplated commercialization of our product candidates. We can give no assurances that such patents can be avoided, invalidated or licensed. With respect to any infringement claim asserted by a third party, we can give no assurances that we will be successful in the litigation or that such litigation would not have a material adverse effect on our business, financial condition, results of operation or prospects. In the event of a successful claim against us for infringement or misappropriation of a third party's proprietary rights, we may be required to:

• Pay damages, including up to treble damages, and the other party's attorneys' fees, which may be substantial;

• Cease the development, manufacture, marketing and sale of products or use of processes that infringe the proprietary rights of others;

• Expend significant resources to redesign our products or our processes so that they do not infringe the proprietary rights of others, which may not be possible;

• Redesign our products or processes to avoid third-party proprietary rights, which means we may suffer significant regulatory delays associated with conducting additional clinical trials or other steps to obtain regulatory approval; and

• Obtain one or more licenses arising out of a settlement of litigation or otherwise from third parties for the infringed proprietary rights, which may not be available to us on acceptable terms or at all.

Furthermore, litigation with any third party, even if the allegations are without merit, would likely be expensive and time-consuming and divert management's attention.

In addition, we may have to undertake costly litigation to enforce any patents issued or licensed to us or to determine the scope and validity of another party's proprietary rights. An adverse outcome in litigation or interference or other proceeding in any court or patent office could materially adversely affect our ability to develop and commercialize our products.

In addition to patents, we and our partners also rely on trade secrets and proprietary know-how. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, third parties may still obtain this information or come upon this same or similar information independently. If any of these events occurs, or we otherwise lose protection for our trade secrets or proprietary know-how, the value of this information may be greatly reduced.

If we are unable to successfully manage our growth, our business may be harmed.

Our success will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and on our administrative,

operational and financial resources. To manage this growth, we must expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business would be harmed.

Certain of our business practices are subject to scrutiny by regulatory authorities, as well as to lawsuits brought by private citizens under federal and state laws. Failure to comply with applicable law or an adverse decision in lawsuits may result in adverse consequences to us.

The laws governing our conduct in the United States are enforceable by criminal, civil and administrative penalties. Violations of laws such as the Federal Food, Drug and Cosmetic Act, the False Claims Act and the Anti-Kickback Law and the Public Health Service Act, and any regulations promulgated under their authority, may result in jail sentences, fines or exclusion from federal and state programs, as may be determined by Medicare, Medicaid and the Department of Defense and other regulatory authorities as well as by the courts. There can be no assurance that our activities will not come under the scrutiny of regulators and other government authorities or that our practices will not be found to violate applicable laws, rules and regulations or prompt lawsuits by private citizen "relators" under federal or state false claims laws.

RISKS RELATED TO OUR BUSINESS AND INDUSTRY

We currently have only one product candidate, which is at an early stage of development and may not be successfully developed or commercialized.

We currently have one product candidate, which is in the early stage of development and will require substantial further capital expenditures, development, testing, and regulatory clearances prior to commercialization. Of the large number of drugs in development, only a small percentage successfully complete the FDA regulatory approval process and are commercialized. Accordingly, even if we are able to obtain the requisite financing to fund our development programs, we cannot assure you that our current product candidate or any future product candidates will be successfully developed or commercialized. If we are unable to develop or unable to receive regulatory approval for or unsuccessfully commercialize our product candidates, we will not be able to generate product revenues.

Because the results of preclinical studies and early clinical trial are not necessarily predictive of future results, the advancement of our product candidates into clinical trials may not have favorable results in later clinical trials, if any, or receive regulatory approval.

Pharmaceutical or biologic development has inherent risk. We will be required to demonstrate through well-controlled clinical trials that our product candidates are effective with a favorable benefit-risk profile for use in their target indications before we can seek regulatory approvals for their commercial sale. Success in early clinical trials does not mean that later clinical trials will be successful as a product candidate in later-staged clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. In addition, only a small percentage of drugs under development result in submission of a BLA to the FDA and even fewer are approved for commercialization.

Any product candidate we may advance into clinical development is subject to extensive regulation, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our current product candidate or any future product

candidate is subject to extensive regulation by the FDA in the United States and by comparable health authorities in foreign markets. In the United States, we are not permitted to market any product candidates until we receive approval of a BLA from the FDA. The process of obtaining BLA approval is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. Approval policies or regulations may change and the FDA has substantial discretion in the pharmaceutical approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

The FDA or and other regulatory agencies can delay, limit or deny approval of a product candidate for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA that a product candidate is safe and effective for any indication;
- the FDA may not accept clinical data from trials which are conducted by individual investigators or in countries where the standard of care is potentially different from the United States;
- the results of clinical trials may not meet the level of statistical significance required by the FDA for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from preclinical studies or clinical trials;
- the FDA may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we or our collaborators contract for clinical and commercial supplies; or
- the approval policies or regulations of the FDA may significantly change in a manner rendering our clinical data insufficient for approval.

With respect to foreign markets, approval procedures vary among countries, and, in addition to the aforementioned risks, can involve additional product testing, administrative review periods and agreements with pricing authorities. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us from commercializing our product candidates.

Any product candidates we advance into clinical trials may cause unacceptable adverse events or have other properties that may delay or prevent their regulatory approval or commercialization or limit their commercial potential.

Unacceptable adverse events caused by any product candidate that we advance into clinical trials could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications and markets. This in turn, could prevent us from commercializing the affected product candidate and generating revenues from its sale.

We have not yet begun clinical testing of any product candidate for the treatment of the indications for which we intend to seek product approval in humans, and we currently do not know the extent of adverse events, if any, that will be observed in patients who may receive our current product candidate or any future product candidates. If any of our product candidates causes unacceptable adverse events in clinical trials, we may not be able to obtain regulatory approval or commercialize such product.

We may experience delays in the commencement of our clinical trials or in the receipt of data from third parties, which could result in increased costs and delay our ability to pursue regulatory approval.

Delays in the commencement of clinical trials and delays in the receipt of data from preclinical or clinical trials conducted by third parties could significantly impact our product development costs and the time required to commercialize our products. Before we can initiate clinical trials in the United States for any product candidate, we need to submit the results of preclinical testing to the FDA as part of an IND, along with other information including information about product chemistry, manufacturing and controls and our proposed clinical trial protocol.

We currently plan to rely on preclinical, clinical and quality data from third parties for the IND submission for our current product candidate and any future product candidates. If we are unable to use such data for any reason, including reasons outside of our control, it will delay our plans for IND filings, and clinical trial plans. If those third parties do not make this data available to us, we will likely, on our own, have to develop all the necessary preclinical and clinical data which will lead to additional delays and increase the costs of our development of product candidates. In addition, the FDA may require us to conduct additional preclinical testing for any product candidate before it allows us to initiate the clinical testing under any IND, which may lead to additional delays and increase the costs of our preclinical development. Even assuming an active IND for a product candidate, clinical trials can be delayed for a variety of reasons, including delays in:

- obtaining regulatory clearance to commence a clinical trial;
- identifying, recruiting and training suitable clinical investigators;
- reaching agreement on acceptable terms with prospective contract research organizations ("CROs") and trial sites, the terms of which can be subject to extensive negotiation, may be subject to modification from time to time and may vary significantly among different CROs and trial sites;
- obtaining sufficient quantities of a product candidate for use in clinical trials;
- obtaining IRB or ethics committee approval to conduct a clinical trial at a prospective site;
- identifying, recruiting and enrolling patients to participate in a clinical trial; and
- retaining patients who have initiated a clinical trial but may withdraw due to adverse events from the therapy, insufficient efficacy, fatigue with the clinical trial process or personal issues.

Any delays in the commencement of our clinical trials will delay our ability to pursue regulatory approval for our product candidates. In addition, many of the factors that cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate.

Delays in the completion of clinical testing could result in increased costs to us and delay our ability to generate product revenues.

Once a clinical trial has begun, patient recruitment and enrollment may be slower than we anticipate. Clinical trials may also be delayed as a result of ambiguous or negative interim results. Further, a clinical trial may be suspended or terminated by us, an IRB, an ethics committee or a Data Monitoring Committee overseeing the clinical trial, any of our clinical trial sites with respect to that site or the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues or any determination that the clinical trial presents unacceptable health

risks; and

- lack of adequate funding to continue the clinical trial.

Changes in regulatory requirements and guidance also may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination, which may impact the costs, timing and the likelihood of a successful completion of a clinical trial. If we experience delays in the completion of, or if we must terminate, any clinical trial of any product candidate, our ability to obtain regulatory approval for that product candidate will be delayed and the commercial prospects, if any, for the product candidate may suffer as a result. In addition, many of these factors may also ultimately lead to the denial of regulatory approval of a product candidate.

We intend to rely on third parties to conduct our clinical trials. If these third parties do not meet our deadlines or otherwise conduct the trials as required, our clinical development programs could be delayed or unsuccessful and we may not be able to obtain regulatory approval for or commercialize our product candidates when expected or at all.

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. We intend to use CROs to conduct our planned clinical trials and will rely upon medical institutions, clinical investigators and contract research organizations and consultants to conduct our trials in accordance with our clinical protocols. Our future CROs, investigators and other third parties play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials.

There is no guarantee that any CROs, investigators and other third parties upon which we rely for administration and conduct of our clinical trials will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fail to meet expected deadlines, fail to adhere to our clinical protocols or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated. If any of our clinical trial sites terminate for any reason, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be jeopardized.

If our competitors develop treatments for the target indications of our product candidates that are approved more quickly, marketed more successfully or demonstrated to be more effective than our product candidates, our commercial opportunity will be reduced or eliminated.

We operate in highly competitive segments of the biotechnology and biopharmaceutical markets. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Our current product candidate, if successfully developed and approved, will compete with established therapies, as well as new treatments that may be introduced by our competitors. Many of our competitors have significantly greater financial, product development, manufacturing and marketing resources than us. Large pharmaceutical companies have extensive experience in clinical testing and obtaining regulatory approval for drugs. In addition, many universities and private and public research institutes are active in medical research, some in direct competition with us. We also may compete with these organizations to recruit management, scientists and clinical development personnel. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. New developments, including the development of other pharmaceutical technologies and

methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace. Developments by competitors may render our product candidates obsolete or noncompetitive. We will also face competition from these third parties in recruiting and retaining qualified personnel, establishing clinical trial sites and patient registration for clinical trials and in identifying and in-licensing new product candidates.

We rely completely on third parties to manufacture our preclinical and clinical pharmaceutical supplies and expect to continue to rely on third parties to produce commercial supplies of any approved product candidate, and our dependence on third party suppliers could adversely impact our business.

We are completely dependent on third party manufacturers for product supply. If a third party becomes unable or unwilling to deliver sufficient quantities of a product candidate to us on a timely basis and in accordance with applicable specifications and other regulatory requirements, there could be a significant interruption of our supply, which would adversely affect clinical development and commercialization of the product. Furthermore, if a third-party supplier or any other contract manufacturers cannot successfully manufacture material that conforms to our specifications and with FDA regulatory requirements, we will not be able to secure and/or maintain FDA approval for our product candidates.

We will also rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our anticipated clinical trials. There are a small number of suppliers for certain capital equipment and raw materials that are used to manufacture our product candidates. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Any significant delay in the supply of a product candidate or the raw material components thereof for an ongoing clinical trial could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates.

We do not expect to have the resources or capacity to commercially manufacture any of our proposed products, if approved, and will likely continue to be dependent upon third party manufacturers. Our dependence on third parties to manufacture and supply us with clinical trial materials and any approved products may adversely affect our ability to develop and commercialize our products on a timely basis.

If we are unable to establish sales and marketing capabilities or fail to enter into agreements with third-parties to market and sell any products we may successfully develop, we may not be able to effectively market and sell any such products and generate product revenue.

We do not currently have the infrastructure for the sales, marketing and distribution of any product candidates, and must build this infrastructure or make arrangements with third parties to perform these functions in order to commercialize any products that we may successfully develop. The establishment and development of a sales force, either by us or jointly with a development partner, or the establishment of a contract sales force to market any products we may develop will be expensive and time-consuming and could delay any product launch. If we, or our development partners, are unable to establish sales and marketing capability or any other non-technical capabilities necessary to commercialize any products we may successfully develop, we will need to contract with third parties to market and sell such products. We may not be able to establish arrangements with third-parties on acceptable terms, if at all.

If any product candidate that we successfully develop does not achieve broad market acceptance among physicians, patients, healthcare payors and the medical community, the revenues that it generates from their sales will be limited.

Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of our product candidates by third-party payors, including government payors, generally is also necessary for commercial success. The degree of market acceptance of any approved products will depend on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the clinical indications for which the product is approved;
- acceptance by physicians, major operators of hospitals and clinics and patients of the product as a safe and effective treatment;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including its use outside the approved indications;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse events;
- the effectiveness of our sales and marketing efforts; and
- unfavorable publicity relating to the product.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate sufficient revenue from these products and may not become or remain profitable.

Healthcare reform and restrictions on reimbursements may limit our financial returns.

Our ability or the ability of our collaborators to commercialize any of our product candidates that may receive the requisite regulatory approval may depend, in part, on the extent to which government health administration authorities, private health insurers and other organizations will reimburse consumers for the cost of these products. These third parties are increasingly challenging both the need for and the price of new drug products. Significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Adequate third-party reimbursement may not be available for our product candidates to enable us or our collaborators to maintain price levels sufficient to realize an appropriate return on their and our investments in research and product development.

We use biological materials and may use hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.

We may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. Our operations also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage and our property and casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the

event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

RISKS RELATING TO OUR SECURITIES, OUR MANAGING MEMBERS AND FORWARD LOOKING STATEMENTS

You may not be able to sell or transfer your units.

You should not plan on being able to readily transfer and/or resell your units. Currently there is no market or liquidity for the units and the Company does not have any plans to list the units or any other equity securities on an exchange or other secondary market. The units have not been registered under the Securities Act of 1933, as amended, nor is any such registration contemplated. The sale or transfer of units is subject to certain contractual restrictions contained in the Company's Operating Agreement. Investors may not be able to liquidate their investment in the event of emergency or for any other reason. Purchase of units is suitable only for individuals and entities that have no need for liquidity with respect to their investment.

Our Managing Members may have limits on the time they have to devote to the Company.

The success of the Company will depend in part upon the skill and expertise of the Managing Members. The Managing Members and their affiliates may have conflicts of interest in allocating management and administrative time, services, and functions among various future entities, as well as other business ventures in which they are or may become involved. The Managing Members and their affiliates will devote only so much of their time to the business of the Company as in their judgment is reasonably required. All material actions with respect to the Company will require the consent of both Managing Members, which may lead to deadlocks and delay or impede important company actions and decisions.

Any forecasts we make about our operations may prove to be inaccurate.

We must, among other things, determine appropriate risks, rewards, and level of investment in our product candidates, respond to economic and market variables outside of our control, respond to competitive developments and continue to attract, retain, and motivate qualified employees. There can be no assurance that we will be successful in meeting these challenges and addressing such risks and the failure to do so could have a materially adverse effect on our business, results of operations, and financial condition. Our prospects must be considered in light of the risks, expenses, and difficulties frequently encountered by companies in the early stage of development. As a result of these risks, challenges, and uncertainties, the value of your investment could be significantly reduced or completely lost.

BUSINESS

COMPANY OVERVIEW

Intrommune is a New York City-based biotechnology company dedicated to simplifying allergy immunotherapy. Intrommune's core technology enables immunotherapeutic agents to be delivered in a specially formulated toothpaste designed to incorporate and stabilize allergenic proteins, representing a new therapeutic approach for the treatment of peanut and other food allergies. Conducting allergy immunotherapy via teeth brushing is referred to as oral mucosal immunotherapy (OMIT). OMIT delivers allergenic proteins to the areas of the oral cavity, potentially driving the immune system toward tolerance without ingestion of the allergen. OMIT may address a significant health care need in the industrialized world, where the spread of food allergies has been characterized as an "epidemic."

The Problem

Food allergies are a significant and growing epidemic. Approximately 8% of children and 11% of US adults (far more than earlier estimates of 5% of adults in the US) are food allergy sufferers. This equates to approximately 32 million people in the US suffering from food allergies, more than the previously combined estimates for both the US and EU. In addition, the rate of sufferers requiring emergency room visits and suffering anaphylaxis more than doubled from 2005 to 2014. There are many common foods that can trigger allergies, with peanut being one of the most prevalent and most commonly associated with severe outcomes and life-threatening events. Unfortunately, there are currently no approved therapies for treating food allergies. Patients with food allergies typically manage their condition via scrupulous dietary avoidance. In the event that accidental exposure to food allergens induces a serious allergic reaction in a person with food allergy, symptom-management interventions, such as antihistamines or injectable epinephrine, are the only recourse available.

The Intrommune Solution

Intrommune's approach is designed to desensitize patients' immune systems to allergens of specific foods. OMIT is a specially formulated toothpaste that contains low doses of specific allergens from allergy triggering foods, such as peanut. As a user brushes their teeth daily with OMIT, the food allergens are brought into contact with immune cells of the oral cavity. In theory, over time, this process gradually desensitizes the patient's immune system to specific allergens. Such specific desensitization may then reduce the risk of having an allergic reaction upon accidental exposure or reduce the severity of resultant allergic symptoms, should an allergic reaction occur.

The principle of immunotherapy is well accepted and has been in use for over 100 years for treating respiratory allergies, though typically via subcutaneous injection in a clinical setting or through sublingual immunotherapy (SLIT) drops applied under the tongue. The OMIT platform is an improved delivery platform that builds upon food allergy studies using SLIT and oral immunotherapy (OIT) allergen ingestions studies. In addition, a pilot proof of concept study has shown OMIT can be used to treat IgE-mediated respiratory allergies, such as those commonly associated with seasonal and year-round triggers such as tree and grass pollen, dust mites, and indoor pets.

OMIT may offer three key advantages over other immunotherapy methods, including those of other recent entrants in this space: it may be safer than oral immunotherapy (OIT) because allergens are not ingested; it may be more efficacious than sublingual immunotherapy (SLIT) and epicutaneous immunotherapy (EPIT) because allergens are exposed to a greater mucosal surface area within the oral cavity; and it may foster better treatment adherence, due to expected ease of incorporation into a patient's everyday routine. The simplicity of this potential treatment suggests that it could be easily prescribed by allergy and immunology specialists, opening up a large market for allergy treatment.

Intrommune aims to provide a life-changing treatment option to patients with food allergies seeking a safe way to attain long-term desensitization. Through company-led research and development, strategic partnerships, and targeted investments, Intrommune is positioned to develop this technology and potentially change the lives of allergy sufferers worldwide.

INT301 Program Overview

Intrommune's OMIT platform is intended to reduce the burden and anxiety experienced by food-allergic patients and their families. The company's lead OMIT product is INT301, an investigational biologic for the treatment of pediatric and adult patients with peanut allergy. INT301 is based on the well-known approach of specific desensitization that has been used for over 100 years for other allergic disorders. The product is intended to significantly raise patients' immune threshold beyond that which can trigger a potentially dangerous allergic reaction via accidental exposure. This additional protection is important for relieving the persistent anxiety that peanut allergic patients can perceive, as small amounts of peanut protein can occasionally be present in foods that are thought to be peanut-free.

Peanut allergy is a life-threatening disease with no approved medical treatment options. Avoidance of peanut consumption is typically practiced by affected individuals, coupled with reliance on antihistamines or epinephrine injection in the event of symptoms triggered by accidental exposure. Strict dietary avoidance is often expensive and hard to achieve and accidental exposure to peanut allergens is common. The resulting risk and anxiety for patients and their families can be significant and is a highly motivating force in seeking out therapy. There is a particularly high unmet need for pediatric peanut allergy sufferers who spend most of the day at school or elsewhere at a distance from immediate parental oversight.

MARKET ANALYSIS

The Current State of Food Allergy Immunotherapy

Allergy immunotherapy is a disease-modifying technique for treating the immune system hypersensitivity that is the underlying cause of allergic disorders. Allergic symptoms occur after a patient has encountered a food or environmental substance multiple times. Upon initial exposure(s), the immune system of atopic patients – patients who are genetically prone to allergy – treats the foreign substance as an invader, programming the immune system to "recognize" and "attack" it as though it is a pathogen in future encounters. Symptoms of allergy are a result of the inflammatory response the body launches in order to destroy the harmless but misrecognized substance.

While environmental allergies typically cause itchy eyes and a stuffy or runny nose, immune responses to food allergens can result in anaphylaxis, a multi-system, potentially lethal condition that can produce swelling of the respiratory mucosa, angioedema, vomiting and diarrhea, shock, and death. Environmental allergies are a costly nuisance, but food allergies are a deadly public health emergency.

Allergy immunotherapy is a disease modifying treatment that reduces allergic sensitivity through exposing the immune system to allergens in a medically monitored, controlled way. It has been used to reprogram the immune system of allergic individuals for more than a century. When allergens are exposed to the body in small, regular doses, they are taken up by antigen-presenting cells and presented to the immune system, shifting the cytokine pathway from a Th-2 allergenic response to a Th-1 tolerogenic response. In epithelial and mucosal tissue, Langerhans Cells (LCs) are the key type of antigen-presenting cell facilitating the gradual development of tolerance.

Because exposure to food allergens has the potential to initiate systemic inflammatory reactions in afflicted individuals, allergy immunotherapy generally employs regimens of gradual introduction, whereby increasing amounts of food allergen are delivered on a regular schedule over a period of

weeks. Each dose during this “up-titration” or “step-up” period is designed to contact the immune system with enough allergens to support gradual development of immunotolerance while remaining below the threshold for triggering allergic symptoms. The step-up phase continues until a predetermined “maintenance” dose is achieved, which continues to be administered regularly. This maintenance dose is intended to provide allergen protection to an amount greater than what is expected to be ingested by a patient accidentally, i.e., the level of tolerance that protects the patient from accidental exposure.

The goal of food allergy immunotherapy is to protect the patient from a serious reaction in the event of accidental exposure through desensitization, which is the ability to tolerate an increased amount of the triggering allergen that would be expected via accidental exposure. Allergy immunotherapy studies use food challenge to demonstrate the degree of desensitization. The common endpoint in these approaches is the degree of desensitization in the treatment group compared to that of a placebo control group. In the case of peanuts, often 300mg of peanut protein, roughly equivalent to one to two peanut kernels, is the target that translates to a clinically meaningful reduction in the risk of serious reaction to the food.

Following a course of immunotherapy, the ability to maintain desensitization to the food allergen is known as sustained unresponsiveness. The currently available published literature defining and characterizing sustained unresponsiveness remains limited at this early stage. The length of time off therapy that would represent clinically meaningful benefit remains undefined. Therefore, the clinical parameters that should delineate sustained unresponsiveness and appropriate study endpoints to demonstrate it have yet to be established.

In the food-allergic individual, tolerance is the complete and permanent resolution of clinical response following exposure to any amount of the identified allergenic food. Tolerance has not yet been demonstrated in any controlled trial of food allergy immunotherapy to date. Similar to sustained unresponsiveness, the clinical parameters that should be used to demonstrate tolerance in clinical trials have not been established.

Subcutaneous immunotherapy (SCIT) is the traditional mode of performing allergy immunotherapy. For respiratory allergies, SCIT is a 3 to 5-year process that requires weekly doctor’s office visits for shots for approximately 1 year as the dose is gradually increased (called the “escalation phase”) followed by 2 to 4 additional years of monthly “maintenance dose” shots. SCIT is not used for the treatment of food allergies due to the high likelihood of multi-system allergic reactions, called anaphylaxis, which can lead to obstructed breathing, shock, and death.

Sublingual immunotherapy (SLIT) is the administration of allergen extracts under the patient’s tongue. For respiratory allergies, SLIT requires a shorter up-dosing period and can be done largely at home for the same 3 to 5-year duration as SCIT. SLIT has a more favorable safety profile, but it is not widely available beyond clinical studies, due to the variability and limitations of dosing and problems with patient adherence that cause concern about the risk of adverse events.

Oral immunotherapy (OIT) is used for food allergy. In OIT, patients eat controlled “doses” of the food they are allergic to daily. OIT is mainly used by clinicians to desensitize patients to food allergies in clinical trials. OIT is not used to treat food allergies outside of clinical trials because there is no standard protocol and the rate of anaphylaxis remains high. In studies, GI side effects have been reported in up to 45% of doses and serious anaphylactic reactions in up to 1% of doses. Aimmune Therapeutics has developed a standardized version of OIT they refer to as characterized oral desensitization immunotherapy or CODIT™. Aimmune published pivotal Phase III results for peanut

allergy in November 2018 and submitted the corresponding BLA for CODIT in children in December 2018. The FDA approved Aimmune's OIT Peanut (Arachis hypogaea) Allergen Powder-dnfp product, called Palforzia, to mitigate allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanuts on January 31, 2020.

A systematic review and meta-analysis of efficacy and safety of OIT in patients with peanut allergy found with high-certainty that available peanut oral immunotherapy (OIT) regimens significantly increase allergic and anaphylactic reactions over avoidance or placebo, despite effectively inducing desensitisation. Safer peanut allergy treatment approaches are needed.

Epicutaneous immunotherapy (EPIT) is a new strategy for treating food allergies. DBV Technologies has developed Viaskin™ Peanut, that exposes allergens to the skin using a proprietary, hydrostatic adhesive patch and powdered allergens. Research is ongoing concerning the ideal duration of EPIT treatment. On December 19, 2018, the company announced it withdrew its BLA application for peanut allergy. The company said the issue related to insufficient data on manufacturing procedures and quality control. On October 4, 2019, the company announced that the FDA had accepted the Viaskin Peanut BLA for filing with a target action date of August 5, 2020. On March 16, 2020, the company announced that the FDA had informed the company that during its ongoing review of the BLA for investigational Viaskin, it had identified questions regarding efficacy, including the impact of patch-site adhesion. The Allergenic Products Advisory Committee (APAC) meeting to discuss the BLA previously scheduled for May15, 2020 was delayed or cancelled. The target action date of August 5, 2020 may be extended.

Oral mucosal immunotherapy (OMIT) delivered via Intrommune's OMIT platform delivers allergens via a specially formulated, fully-functional toothpaste base that incorporates and stabilizes allergenic proteins. Patients receive their daily dose of allergen while they brush their teeth. Like SLIT, OMIT presents allergens to oral mucosal tissue. OMIT promises superior results because it exposes a much wider area of the oral mucosal tissues to the allergens, including the vestibule where oral Langerhans cells are found in the highest concentration in the oral cavity. Preliminary studies suggest this may produce a faster initiation of response with a more favorable safety profile than SLIT.

Market Size

There has been a global rise in food allergies over the last decade. In the United States, it had been estimated that 15 million Americans have food allergies – 6 million children and 9 million adults. Two research publications since December 2018 have shown that those numbers are substantially higher than previously estimated, with approximately 32 million Americans with food allergies. In addition, adult onset food allergies are becoming more frequent. The economic problem posed by food allergies is significant. A 2013 survey of the economic impact of childhood food allergies in the U.S. found that direct medical costs (clinician visits, emergency room visits, and hospitalizations) accounted for $4.3 billion each year. The survey also noted that indirect costs to families of pediatric food allergy sufferers (lost labor, out of pocket expenses, and opportunity costs) totaled $20.5 billion annually – an overall economic cost totaling $24.8 billion, or $4,184 per food allergic child per year. Eight common foods – peanut, tree nut, wheat, milk, egg, soy, fish and shellfish – account for 90% of all food allergies. Peanut alone is responsible for up to 25% of childhood food allergies. Food allergies present huge financial costs, as well as emotional and social costs for food allergy families.

Despite the high and growing incidence of allergic disease, however, the past few decades have seen few improvements in allergy therapeutics. There is currently no disease-modifying treatment for food

allergies. Immunotherapy remains largely an experimental treatment for food allergies. The only options available to patients are avoidance of the food and the use of emergency rescue medications when avoidance fails. The 15 million Americans with food allergies today are desperate for solutions and highly motivated to commit to new therapies when they enter the market.

Market Growth

The allergy therapeutics market is anticipated to continue undergoing robust growth both in the US and abroad due to a continuing increase in rates of allergic disease. According to the World Allergy Organization (WAO), an estimated 30-40% of the global population suffers from allergic disease. That number is growing in both developed and developing countries, and allergies (particularly food allergies) seem to be increasing in severity.

Food allergies are on the rise, with rates of peanut allergy tripling in children from 1997 to 2008. Allergies to the rest of the top 8 allergens are increasing as well, causing an estimated 200,000 hospital emergency room visits a year in the US For example, researchers found an annual average increase of 29% in emergency department visits for food-induced anaphylaxis in Illinois between 2008 and 2012. Hospital admissions for food allergies have risen dramatically, nearly doubling nationally from 1998-2000 to 2001-2003 and then more than doubling from 2001-2003 to 2004-2006, for a total of over 9,000 hospital admissions each year in the US by 2006. There is no sign that the rising rate and burden of allergies will slow down until a disease-modifying treatment with long-term efficacy reaches the market to stem the epidemic.

Market Drivers

Shortcomings of existing treatments

The global rise of food allergies and lack of widely available, easy to use treatments with long-term efficacy drives a great deal of clinical research. The shortcomings of existing protocols are therefore well documented. Research on allergy immunotherapy for environmental allergies reveals serious compliance challenges that would likely translate to other food allergy therapies in development (SLIT, OIT, CODIT, and EPIT). SCIT and SLIT have been found to be highly effective for environmental allergies when used as directed for the recommended amount of time, but less than 1 in 5 patients complete 3 years of therapy, with as many as half dropping out after 1 year. Shortcomings of SCIT for environmental allergies include the inconvenience of weekly and monthly office visits. Obstacles to SLIT include difficulty of administration (difficult to use droppers and the need to hold the liquid under the tongue for 2 minutes) and low rates of treatment adherence in real-world use. Additionally, the mucosal tissue of the sublingual space has the lowest concentration of oral Langerhans Cells in the mouth, the cells that are most important for driving desensitization. In other words, SLIT delivers allergens to the oral mucosa in the least appropriate area of the mouth.

To date, OIT has been used to treat food allergies primarily in investigational settings. Safety issues have emerged around its use, which have been a primary hurdle to its broader adoption in the clinic. Aimmune's CODIT program is based upon previously-existing investigational research with OIT, though with an aim to reduce the number of adverse events seen in those investigations by batch-release standardization of the naturally-sourced peanut flour used in Palforzia. In OIT studies the contact of the allergen with GI tissues, particularly those of the esophagus during ingestion is suspected to be responsible for the significant number of systemic reactions and AEs. It is noteworthy that Aimmune's CODIT program using standardized batches of peanut flour has exhibited

gastrointestinal side effects that have been a driver of patient dropouts from completed studies with Palforzia.

OMIT is projected to have a safety profile better than OIT and similar to or exceeding SLIT because it does not involve swallowing allergens. OMIT may also address two shortcomings of SLIT: (a) rather than concentrating allergen extracts in a small area and potentially causing irritation, OMIT exposes a wide area of the oral mucosa to allergens, and (b) OMIT is able to incorporate more allergenic protein than SLIT. Based on findings in the literature, it is expected that OMIT will improve efficacy compared to SLIT and reduce gastrointestinal (GI) and systemic symptoms compared to OIT.

The most important expected advantage of OMIT over all other forms of allergy immunotherapy is that the delivery mechanism facilitates long-term patient adherence to treatment. 98% of American's brush their teeth at least once a day. Not only is this anticipated to speed desensitization and improve final outcomes, it may also improve the safety of administering treatment, since it has been documented that reactions often occur when patients resume therapy after missing doses. Another key benefit is that, like SLIT, most doses would be taken at home.

Despite the challenges posed by existing methods, it must be noted that food allergy immunotherapy via SLIT and OIT has consistently been shown to be effective, significantly reducing the allergy symptoms in up to 82% of patients. Additionally, SLIT, which does not involve swallowing allergens, has been shown to have a more favorable safety profile than OIT. The obstacle to widespread adoption is not the effects of the treatment itself, but the challenges of patient adherence, a well-defined dosing schedule, and a patient-friendly delivery mechanism.

Unmet patient need

As many as 32 million people in the United States - including 6 million children - suffer from food allergies, yet no treatment exists outside of clinical trials. Strict avoidance of allergens is the first-line food allergy management technique, followed by epinephrine used as a rescue medication when avoidance fails and a reaction occurs. Avoidance and rescue medications clearly fail US food allergy patients: 200,000 patients go to emergency rooms and over 100 people die from allergic reactions to food each year.

OMIT may offer an important modality for these patients that is easier to use than existing treatments while striking a more favorable balance of safety and efficacy than competitors' products and experimental protocols currently under development.

Increased demand for food allergy treatment

The prevalence of allergies in the US has been rapidly increasing, with 60-80 million Americans now suffering from at least one allergic sensitivity and 32 million with food allergies. There is currently no disease-modifying, long-term treatment for food allergy currently on the market.

Patient advocacy and public opinion are driving demand for better therapies for food allergies. Patient advocacy groups like Kids with Food Allergies (KFA), Food Allergy Research and Education (FARE), and the Food Allergy and Anaphylaxis Connection Team (FAACT) represent patient concerns in this space and keep patients and caretakers up-to-date on new clinical research on food allergies. These groups, along with a handful of individual advocates, have launched the disease onto

the main stage of public health worries in the US and supported rigorous research on food allergy diagnosis and treatment. Heightened awareness and extensive distribution networks for food allergy treatment information make it easy to access a large population of patients with food allergies who are now highly motivated to seek long-lasting treatment.

Competition

Intrommune may face a few competitors in the food allergy immunotherapy space, including Aimmune Therapeutics and DBV Technologies. A number of competitors are pursuing allergy immunotherapy products, although some focus primarily on environmental allergens, including Stallergenes, ALK Abello, Allergopharma, Allergy Therapeutics, Inmunotek, Laboratorios LETI, Anergis, Shionogi, Astellas, and Torii Pharmaceuticals. Another, more distant class of competitors consists of companies who are developing monoclonal antibodies to short-circuit the allergic response, including food allergens; these include GSK, Sanofi/Regeneron, Roche, and Janssen, and Astellas, which is developing a DNA vaccine.

Intrommune is positioned to benefit from the wealth of clinical research data currently available on food allergy desensitization via immunotherapy, in addition to the growing body of science literature on the immune-pathophysiology of allergy. The company has the benefit not only of access to prior academic clinical research, but also of learning from the clinical and regulatory milestones of first movers Aimmune and DBV.

Aimmune Therapeutics

Aimmune Therapeutics' lead product is Palforzia, an OIT system using peanut powder. Their comprehensive approach to allergy immunotherapy is called characterized oral desensitization immunotherapy (CODIT). The peanut powder itself does not meet the FDA definition of "standardized" for allergen biologics because no standard has been set for peanut powders. Aimmune instead characterizes (measures the concentrations of) 3 of the 9 known allergenic peanut proteins prior to batch release. The specialized powder is then administered via a protocol with defined doses and escalation periods. The stated goal for their product line is to develop desensitization treatments to protect people with food allergies by potentially making accidental exposures less dangerous.

Aimmune's technology received FDA approval on January 31, 2020 for its peanut allergy desensitization product Palforzia and has products for egg and milk in development. ARC001, the Phase IIa trial of Palforzia, was initiated with 55 subjects. Of the 29 on the active treatment arm, 23 completed the trial; the 6 discontinuations (21%) were due to gastrointestinal side effects and compliance issues. Patients who completed ARC001 were invited to participate in the Phase IIb ARC002 to test the long-term efficacy and safety of Palforzia.

Results of their Phase III for Palforzia were published in December 2018. The drug was effective in 2/3 of treated peanut allergic children, with about 20% of them exiting the study before completing. There were adverse side effects in more than 95 percent of treated patients, with epinephrine use in approximately 14% of patients in the active treatment drug group, 2.4 percent having severe adverse events and 1.1 percent experiencing serious adverse events. In addition, about 11.6 percent of patients dropped out of the study because of side effects, compared to 2.4 percent in the placebo group.

Aimmune benefits from a close relationship with leading researchers and with the patient advocacy organization Food Allergy Research and Education (FARE), an early investor in the company. The

~20% dropout rate from the active arm of the Palforzia trials, however, suggests that the same safety concerns that have plagued non-proprietary use of OIT continue to be an issue, despite Aimmune's CODIT approach.

An OMIT approach to peanut allergy desensitization using the OMIT platform is expected to reduce the risk and occurrence of gastrointestinal side effects, because patients would not swallow the daily dose of allergen, reducing contact with GI mucosa and thereby reducing sensitization of this tissue. This has already been demonstrated in a 2013-2014 pilot study using OMIT to desensitize allergic rhinitis patients with environmental allergies. In this study, allergy immunotherapy via OMIT in which toothpaste and allergens were spit out at the end of daily treatment produced fewer GI side effects compared to a SLIT protocol.

DBV Technologies

DBV Technologies is developing a technology platform called Viaskin for delivery of allergy immunotherapy using an electrostatic patch that delivers allergens to the body through the skin, a technique referred to as epicutaneous immunotherapy (EPIT). When placed on the skin, the patch creates a condensation chamber, solubilizing dry antigen contained in the patch and facilitating penetration of the antigen into the upper layers of the epidermis. Antigen-presenting cells, called Langerhans cells, are theorized to take up the allergenic proteins and present them to the immune system, driving desensitization to allergens over time.

DBV's Viaskin Peanut product Phase IIb study (OLFUS-VIPES) results were presented at the World Allergy Organization's (WAO) World Allergy Congress (WAC) in October 2016. This multinational trial started as a Phase IIa study with 171 adult and pediatric subjects in 21 sites in North American and Europe. 83% of pediatric participants in the blinded Phase IIa study rolled into the open-label Phase IIb study. Top-line results in patients 6 to 11 years of age showed 53.6% response rate after 12 months of treatment, 80.0% response rate after 24 months of treatment, and 83.3% response rate after 36 months of treatment.

DBV's subsequent Phase III study in peanut allergic children evaluated the safety and efficacy of Viaskin Peanut in children four to 11 years of age. Topline interim results in October 2017 showed a statistically significant response with a favorable tolerability profile, with 35.3% of patients responding to Viaskin Peanut after 12 months of treatment as compared to 13.6% of patients in the placebo arm. However, the primary endpoint, which evaluates the 95% confidence interval (CI) in the difference in response rates between the active and placebo arms, fell short of the lower bound of the pre-determined CI. In December 2018, the company voluntarily withdrew its Viaskin Peanut BLA application following discussions with FDA regarding insufficient data on manufacturing procedures and quality controls. On October 4, 2019, the company announced that the FDA had accepted the Viaskin Peanut BLA for filing with a target action date of August 5, 2020. On March 16, 2020, the company announced that the FDA had informed the company that during its ongoing review of the BLA for investigational Viaskin, it had identified questions regarding efficacy, including the impact of patch-site adhesion. The Allergenic Products Advisory Committee (APAC) meeting to discuss the BLA previously scheduled for May15, 2020 was delayed or cancelled. The target action date of August 5, 2020 may be extended.

Other Immunotherapies

Astellas is developing a short-course (4 shot) immunotherapy technique using Immunomic Therapeutics' LAMP-Vax™ DNA vaccine technology. In January 2015, Immunomic and Astellas entered into an exclusive license agreement for Astellas to develop and commercialize a LAMP-Vax product for Japanese cedar allergy in Japan. In October 2015, Astellas acquired the worldwide rights to commercialize LAMP-Vax products for allergy, including peanut allergy.

Monoclonal Antibodies for Allergic Diseases

To date, attempts to use monoclonal antibodies for allergic diseases have yielded disappointing results and high rates of adverse events. There are a number of such products that have recently come to market or are currently under development. Rather than desensitize patients to a/several specific allergen(s), this class of technology aims to dampen the immune allergic response to all allergens by binding to molecules (typically interleukins) to short-circuit atopic and autoimmune responses.

Lead among these products for food allergy is Roche/Genentech and Novartis' Xolair (omalizumab), an anti-IgE antibody which was released to the US market in 2003. Initially developed for allergic asthma resistant to other therapies, several studies have examined its use in food allergy, including its use as an adjuvant to oral immunotherapy for peanut allergies. Due to the injection delivery, high price, efficacy and side effects profile, however, it has not been widely adopted.

A number of other monoclonal antibodies that may have an impact on allergic diseases (including asthma) are on the market (Janssen's anti-TNF-alpha Remicade (infliximab), Sanofi and Regeneron's anti-IL-4 dipilumab) and in development (GSK's anti-IL-5 mepolizumab).

Intrommune Competitive Advantage

OMIT is designed to be the most patient-friendly allergy immunotherapy platform, with potential efficacy on par or superior than with OIT and potential safety on par or better than with EPIT. The immunotherapy approach has been demonstrated to work as a disease-modifying treatment for allergies for over a century. OMIT makes immunotherapy part of the patient's daily dental hygiene routine, thus aiming to overcome the adherence problem characteristic of antigen specific immunotherapy.

The OMIT delivery mechanism – exposing allergens to the vestibule which contains a high concentration of antigen-presenting cells (oral Langerhans Cells) – is anticipated to both increase efficacy compared to SLIT and reduce the GI and systemic side effects that are characteristic of OIT. Finally, Intrommune benefits from the research on OIT and SLIT for food allergies that has been published by academic researchers in the past decade. This research streamlines the process of choosing an appropriate dose and dosing protocol. Intrommune has relationships with several leaders in this area to provide insights on translating previous studies to the development of INT301 and future product candidates. Intrommune is also developing relationships with leading manufacturers of allergen extracts to maintain an unbroken supply of characterized food allergen protein for INT301 and follow-on food allergy products.

INTELLECTUAL PROPERTY & TRADE SECRETS

Intrommune's competitive position will depend upon the ability to obtain and enforce intellectual property rights protecting its OMIT platform technology. Intrommune continues to develop what it considers to be a strong intellectual property portfolio, which it expects will include licenses, patents, design patents, trademarks, trade secrets, and know-how. Intrommune is actively pursuing a broad array of intellectual property protection in the US and North America, as well as significant markets elsewhere including Europe, Australia, China, Japan, Israel, India, Korea, Brazil, Russian Federation (including Eurasia) and Hong Kong. Intrommune believes that its intellectual property portfolio will continue to grow and will effectively protect all food allergy-targeting OMIT products that it envisions.

Intrommune currently has licensed exclusive global food allergy immunotherapy rights to a portfolio that currently consists of patent families initiated from two PCT applications.

Patent Family 1

PCT/US2011/034731 (WIPO Pub. No. WO 2011/137420) "Methods, Articles and Kits for Allergic Desensitization via the Oral Mucosa." This PCT application is being prosecuted in the United States, EU (via the EPO), Japan, China, Hong Kong, India, and Australia.

Following grant of patents from the above PCT application, continuation applications, and divisional applications stemming from the above PCT application are being filed and many are currently under prosecution. Claims and pending claims include methods of desensitizing allergic individuals by use of a toothpaste that contains one or more allergenic proteins, including food allergens such as peanuts, tree nuts, eggs, milk, shellfish, fish, wheat, soy, and their derivatives.

Patent Family 2

PCT/US2014/056562 (WIPO Pub. No. WO 2015/042402) "Toothpaste for Delivering Allergens to the Oral Mucosa." This PCT application is being prosecuted in the United States, EU (via the EPO), Brazil, Japan, Canada, Israel, Russian Federation (including Eurasia) and Korea.

Regional applications stemming from PCT/US2014/056562 have pending claims directed to compositions of fully-functional toothpaste that can stably incorporate allergenic proteins. Pending claims also include methods of formulating such toothpaste compositions for optimal delivery of OMIT.

In addition to patents, Intrommune has and will continue to rely upon unpatented trade secrets, know-how, and continuing technological innovation during pre-clinical and clinical product development to maintain its competitive position. Intrommune protects its proprietary information, in part, using confidentiality agreements with its partners, collaborators, contract manufacturers, suppliers, employees and consultants and invention assignment agreements with its employees. Intrommune also has confidentiality agreements or invention assignment agreements with its partners and selected consultants.

GOVERNMENT REGULATION AND PRODUCT APPROVAL

Government authorities in the United States at the federal, state and local level as well as in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products, or biologics, such as our product candidates. Generally, before a new drug or biologic can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific to each regulatory authority, submitted for review and approved by the regulatory authority.

United States Biologic Product Development Process

In the United States, the Food and Drug Administration ("FDA") regulates biologics under the Federal Food, Drug, and Cosmetic Act, or FDCA, and the Public Health Service Act, or PHSA, and their implementing regulations. Biologics are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Intrommune product candidates must be approved by the FDA through the Biologics License Application, or BLA, process before they may be legally marketed in the United States. The process required by the FDA before a biologic may be marketed in the United States generally involves the following:

- completion of extensive nonclinical, sometimes referred to as pre-clinical laboratory tests, pre-clinical animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an investigation new drug application, or IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND and other clinical trial-related regulations, sometimes referred to as good clinical practices, or GCPs, to establish the safety and efficacy of the proposed product for its intended use;
- submission to the FDA of a BLA;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the product is produced to assess compliance with the FDA's current good manufacturing practice, or cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality, purity and potency;
- potential FDA audit of the pre-clinical and/or clinical trial sites that generated the data in support of the BLA; and

- FDA review and approval of the BLA prior to any commercial marketing or sale of the product in the United States.

The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources and approvals are inherently uncertain.

The data required to support a BLA is generated in two distinct development stages: pre-clinical and clinical. The pre-clinical development stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The conduct of the pre-clinical studies must comply with federal regulations, including GLPs. The sponsor must submit the results of the pre-clinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that could cause the trial to be suspended or terminated. The clinical stage of development involves the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Clinical trials must be conducted in accordance with the FDA's GCPs. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

Clinical trials are generally conducted in three sequential phases that may overlap, known as Phase I, Phase II and Phase III clinical trials. Phase I clinical trials generally involve a small number of healthy volunteers who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate and, if possible, to gain early evidence on effectiveness. Phase II clinical trials typically involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, as well as identification of possible adverse effects and safety risks and preliminary evaluation of efficacy. Phase III clinical trials generally involve large numbers of patients at multiple sites, in multiple countries (from several hundred to several thousand subjects) and are designed to provide the data necessary to demonstrate

the efficacy of the product for its intended use, its safety in use, and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. Phase III clinical trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing. Generally, two adequate and well-controlled Phase III clinical trials are required by the FDA for approval of a BLA.

Post-approval trials, sometimes referred to as Phase IV clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, FDA may condition approval of a BLA on the sponsor's agreement to conduct additional clinical trials to further assess the biologic's safety and effectiveness after BLA approval.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse, findings from other studies suggesting a significant risk to humans exposed to the drug, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important rate increase of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase I, Phase II and Phase III clinical trials may not be completed successfully within any specified period, if at all. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated intervals based on access to certain data from the trial. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate. Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of certain clinical trials of FDA-regulated products, including biologics, are required to register and disclose specified clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. However, there are evolving rules and increasing requirements for publication of all trial-related information, and it is possible that data and other information from trials involving drugs and biologics that never garner approval could require disclosure in the future. In addition, publication policies of major medical journals mandate

certain registration and disclosures as a pre-condition for potential publication, even if not currently mandated as a matter of law. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

United States Review and Approval Process

The BLA review and approval process is lengthy and difficult and the FDA may refuse to approve a BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. If a product receives regulatory approval, the approval may be significantly limited to specific disease and dosages or the indications for use may otherwise be limited, which could restrict commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the produce labeling.

Following trial completion, trial data is analyzed to assess safety and efficacy. The results of pre-clinical studies and clinical trials are then submitted to the FDA as part of a BLA, along with proposed labeling for the product and information about the manufacturing process and facilities that will be used to ensure product quality, results of analytical testing conducted on the chemistry of the product candidate, and other relevant information. The BLA is a request for approval to market the biologic for one or more specified indications and must contain proof of safety, purity, potency and efficacy, which is demonstrated by extensive pre-clinical and clinical testing. The application includes both negative or ambiguous results of pre-clinical and clinical trials as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a significant user fee, which is adjusted on an annual basis. PDUFA also imposes an annual product fee for human drugs and an annual establishment fee on facilities used to manufacture prescription drugs. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business.

Once a BLA has been accepted for filing, which occurs, if at all, sixty days after the BLA's submission, the FDA's goal is to review BLAs within ten months of the filing date for standard review or six months of the filing date for priority review, if the application is for a product intended for a serious or life-threatening condition and the product, if approved, would provide a significant improvement in safety or effectiveness. The review process is often significantly extended by FDA requests for additional information or clarification.

After the BLA submission is accepted for filing, the FDA reviews the BLA to determine, among other things, whether the proposed product candidate is safe and effective for its intended use, and whether the product candidate is being manufactured in accordance with cGMP to assure and preserve the product candidate's identity, strength, quality, purity and potency. The FDA may refer applications for novel drug product candidates or drug product candidates which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should

be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA will likely re-analyze the clinical trial data, which could result in extensive discussions between the FDA and us during the review process. The review and evaluation of a BLA by the FDA is extensive and time consuming and may take longer than originally planned to complete, and we may not receive a timely approval, if at all.

Before approving a BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving a BLA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the BLA identified by the FDA. The Complete Response Letter may require additional clinical data and/or an additional pivotal Phase III clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, pre-clinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information is submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

There is no assurance that the FDA will ultimately approve a product for marketing in the United States and we may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific populations, severities of allergies, and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the BLA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved products. For example, the FDA may require Phase IV testing which involves clinical trials designed to further assess the product's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy, or REMS, to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve the BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

Review and Approval of Combination Products in the United States

Certain products may be comprised of components that would normally be regulated under different types of regulatory authorities, and frequently by different centers at the FDA. These products are known as combination products. Specifically, under regulations issued by the FDA, a combination product may be:

- a product comprised of two or more regulated components that are physically, chemically, or otherwise combined or mixed and
- produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and comprised of drug and device products;
- a drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device or biological where both are required to achieve;
- the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
- any investigational drug, device, or biological packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve' the intended use, indication, or effect.

Our INT301and other OMIT platform product candidates are combination products comprising a device for delivery of a biologic. Under the FDCA, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. That determination is based on the "primary mode of action" of the combination product, which means the mode of action expected to make the greatest contribution to the overall intended therapeutic effects. Thus, if the primary mode of action of a device-biologic combination product is attributable to the biologic product, that is, if it acts by means of a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, the FDA center responsible for premarket review of the biologic product would have primary jurisdiction for the combination product.

Expedited Development and Review Programs

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and nonclinical or clinical data demonstrate the potential to address an unmet medical need. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a fast track product concurrently with the submission of an IND or at any time before a pre-NDA/BLA meeting, and the FDA must determine if the product qualifies for fast track designation within 60 days of receipt of the sponsor's request. Unique to a fast track product, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the Application.

Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review, or review within a six-month timeframe from the date a complete BLA is accepted for filing, if it treats a serious condition and has the potential to provide a significant improvement in safety or effectiveness. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review.

Additionally, a product may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. If the FDA concludes that a drug or biologic shown to be effective can be safely used only if distribution or use is restricted, it will require such post-marketing restrictions as it deems necessary to assure safe use of the drug, such as:

- distribution restricted to certain facilities or physicians with special training or experience; or
- distribution conditioned on the performance of specified medical procedures.

The limitations imposed would be commensurate with the specific safety concerns presented by the product. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

The FDA has broad discretion whether or not to grant these designations, and even if we believe our product candidate is eligible for the fast track, priority review, or accelerated approval designations, we cannot be sure that the FDA would decide to grant it. Even if we do obtain one of these designations, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw these designations if it believes that the designation is no longer supported by data from our clinical development program.

Breakthrough Designation

The Food and Drug Administration Safety and Innovation Act, or FDASIA, amended the FDCA to require the FDA to expedite the development and review of a breakthrough therapy. A product can be designated as a breakthrough therapy if it is intended to treat a serious or life-threatening condition and preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. A sponsor may request that a product candidate be designated as a breakthrough therapy concurrently with the submission of an IND or any time before an end-of-Phase-II meeting, and the FDA must determine if the product candidate qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's request. If so designated, the FDA shall act to expedite the development and review of the product's marketing application, including by meeting with the sponsor throughout the product's development, providing timely advice to the sponsor to ensure that the development program to gather pre-clinical

and clinical data is as efficient as practicable, involving senior managers and experienced review staff in a cross-disciplinary review, assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor, and taking steps to ensure that the design of the clinical trials is as efficient as practicable.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that our product candidates, meet the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if our product candidate qualifies as a breakthrough therapy, the FDA may later decide that the products no longer meet the conditions for qualification.

Pediatric Trials

Under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and efficacy of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. FDASIA requires that a sponsor who is planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within sixty days of an end-of-Phase II meeting or as may be agreed between the sponsor and FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials, and/or other clinical development programs. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of data or full or partial waivers.

Post Marketing Requirements

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

may or may not be received or may result in a lengthy review process. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Any distribution of prescription drug products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act, or the PDMA, a part of the FDCA.

Further, once a product is approved its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP. Moreover, the constituent parts of a combination product retain their regulatory status, for example, as a biologic or device, and as such, we may be subject to additional requirements in the Quality System Regulation, or QSR, applicable to medical devices, such as design controls, purchasing controls, and corrective and preventive action. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. cGMP regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. BLA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market.

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

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the Department of Health and Human Services, the Drug Enforcement Administration, the Consumer Product Safety Commission, the

Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments. In the United States, sales, marketing and scientific/educational programs, among other activities, must also comply with state and federal fraud and abuse laws, data privacy and security laws, transparency laws, and pricing and reimbursement requirements in connection with governmental payor programs, among others. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

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

The failure to comply with regulatory requirements subjects a firm to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, the exclusion from participation in federal and state healthcare programs or refusal to allow a firm to enter into supply contracts, including government contracts and individual imprisonment. In addition, even if a firm complies with FDA and other requirements, new information regarding the safety or efficacy of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

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

International Regulation

In addition to regulations in the United States, there are a variety of foreign regulations governing clinical trials and commercial sales and distribution of any the product candidate. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval.

Litigation

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

DIRECTORS, OFFICERS AND EMPLOYEES

Executive Officers

Michael Nelson - Chief Executive Officer and Managing Member

Michael Nelson has been the Founder or Co-Founder and Chief Executive Officer or Chief Financial Officer of several early stage healthcare companies. Mr. Nelson has served as Chief Executive Officer of Intrommune since 2013. Mr. Nelson previously served as the Chief Financial Officer of Immunovent, LLC, a company developing a novel allergy diagnostic and Allovate, LLC, from which Intrommune is licensing its food allergy oral mucosal immunotherapy platform. Mr. Nelson has over 20 years of investment banking, legal, management and investing experience. Mr. Nelson founded Thea Capital Management, LLC, an advisory firm. Mr. Nelson has been involved as an advisor or investor with mergers and acquisitions, initial and subsequent public offerings of common stock, preferred stock, contingent value rights, and senior and subordinated debt. He has represented and advised both debtors and creditors of a number of distressed companies, both inside and outside of bankruptcy.

Mr. Nelson was an Associate Director at Barclays Capital, where he helped manage a $2 billion proprietary portfolio focused on special situations, including risk arbitrage, and the healthcare sector. Mr. Nelson was also Vice President at ING Capital LLC, where he helped manage a $400 million portfolio. Mr. Nelson was an investment banker at Westwood Capital, LLC and in the health care investment banking group at CIBC World Markets, where he specialized in health care services and information and pharmaceutical technology for private and public offerings and M&A. In this role he managed the execution of such transactions and raised a combined total in excess of $325 million for several companies in the healthcare sector. Mr. Nelson began his career as an attorney with the law firm of Willkie Farr & Gallagher in the Bankruptcy & Business Reorganization department specializing in debtor and creditor representation and structured finance counseling in the securitization and structured finance area. Mr. Nelson also practiced law as a senior associate with Dewey Ballantine. Mr. Nelson received a B.S. in Biology from Cornell University and a J.D. from New York University School of Law. He works and is admitted to practice in New York.

Erick Berglund, PhD - Managing Member

Throughout his professional career Dr. Berglund has had a strong interest in developing life sciences technologies to solve human healthcare problems and to meet unmet medical needs. Since 2012 he has been involved with nucleating and growing a commercial framework to develop oral mucosal immunotherapy (OMIT) for treating various allergic diseases. Intrommune Therapeutics is a key part of this framework that focusses on OMIT treatment of peanut and other food allergies. Dr. Berglund served as the Chief Scientific Officer of Intrommune until March 2020 and since 2013, served as a managing member of Intrommune. Dr. Berglund received his scientific training as a PhD student in the Biochemistry Department of the Johann-Wolfgang-Goethe Universität in Frankfurt, Germany. His thesis work was carried out as an external doctoral candidate while working in the commercial R&D laboratories of Hoechst Marion Roussel (now Sanofi) in Frankfurt. His thesis work involved the development of an in vitro system for identifying compounds that act directly at the level of DNA transcription. Prior to that, he earned his MS degree in Biochemistry from Boston University Medical School researching the regulatory mechanism of cell differentiation and cell-specific gene expression. As a co-founder of Intrommune, Dr. Berglund has been directly involved with strategic licensing, partnering, and development of the relevant patent portfolio. Prior to working on Intrommune Therapeutics, Dr. Berglund held a series of corporate positions with life science

companies that, together, required development of a broad range of skills ranging from biotechnology patent strategy, fostering development partnerships, and strategic medical communication. Since beginning work with the OMIT platform for treating allergic disorders, Dr. Berglund has come to appreciate the enormous unmet healthcare needs in this area, particularly for food allergies.

Indemnification

Under the Company's operating agreement, the Company is to indemnify its members, including its Managing Members, each Member's employees, officers, directors, members, agents and Affiliates (each, an "Indemnified Party") against any losses, liabilities, damages or expenses (including attorney fees and expenses in connection therewith and amounts paid in settlement thereof) to which an Indemnified Party may directly or indirectly become subject in connection with the Company or in connection with any involvement with any person in which the Company has a direct or indirect investment, but only to the extent that such Indemnified Party (a) acted in good faith and (b) was neither grossly negligent nor engaged in willful malfeasance. The Company may, in the sole judgment of the Managing Members, pay the expenses incurred by any such Indemnified Party in connection with any proceeding in advance of the final disposition, so long as the Managing Members receive an undertaking by such Indemnified Party to repay the full amount advanced if there is a final determination that such Indemnified Party did not satisfy any standard set forth in clauses (a) and (b) above or that such Indemnified Party is not entitled to indemnification for other reasons.

Employees

The Company currently has 1 employee in New York.

CAPITALIZATION AND OWNERSHIP

Capitalization

The Company has issued the following outstanding Securities:

Class of Security	Authorized Amount	Outstanding Amount	Voting Rights*	Other Rights
Series A Preferred Membership Units	N/A	1,355,850	Yes	Series A Preferred Units are entitled to priority on distributions or if and upon liquidation with respect to their capital account balances.
Class A Membership Units	N/A	15,154,555	Yes	Class A Units are entitled to priority on distributions or if and upon liquidation with respect to their capital account balances.
Class B Membership Units	N/A	1,046,500	No	After satisfying the Series A Preferred Unit and Class A Unit capital account balances, distributions, including those if and upon liquidation, are allocated to all unit holders ratably.
Warrants to Purchase Series A Preferred Units ("Warrants")	N/A	203,462	No	The Warrants entitle the holder to purchase Series A Preferred Units at an exercise price of $1.00 per Unit. The Warrants expire on October 31, 2021.

*The Company has two Managing Members who have exclusive control over its activities. The Managing Members have the sole and absolute right and authority to act for and on behalf of the Company in connection with all aspects of its business.

Securities issued pursuant to Regulation CF:

Type of security	Class A Membership Units
Amount outstanding	154,555
Voting Rights	Yes
Anti-Dilution Rights	N/A

The Company has the following debt outstanding:

Type of debt	License Obligation
Amount outstanding	$290,264
Interest rate and payment schedule	10% Due 12/31/2021
Describe any collateral or security	Right, title and interest in, to and under certain patent applications.
Maturity date	12/31/2021

The total amount of outstanding debt of the company is $290,264.

The Company has conducted the following prior Securities offerings in the past three years:

Security Type	Amount Sold	Use of Proceeds	Offering Date	Exemption from Registration Used or Public Offering
Series A Preferred Membership Units	$275,000	Research and development, intellectual property, general and administrative expenses	5/2020	4(a)(2)
Class B Membership Units	$1	General and administrative expenses	10/2019	4(a)(2)
Series A Preferred Membership Units and Warrants to purchase Series A Units	$565,850	Research and development, intellectual property, general and administrative expenses	9/2019	4(a)(2)
Series A Preferred Membership Units	$290,365	Research and development, intellectual property, general and administrative expenses	1/2019	4(a)(2)
Series A Preferred Membership Units	$224,635	Research and development, intellectual property, general and administrative expenses	10/2018	4(a)(2)

Class A Membership Units	$154,555	Research and development, intellectual property, and general and administrative expenses	7/2018	Regulation CF
Class A Membership Units	$24.05	General and administrative expenses	4/2017	4(a)(2)
Class A Membership Units	$14.86	General and administrative expenses	11/2016	4(a)(2)
Class A Membership Units	$355.77	General and administrative expenses	1/2016	4(a)(2)

Ownership

Below is the name and ownership of each person, as of June 15, 2020, who is the beneficial owner of 20 percent or more of the Company's outstanding voting equity securities, calculated on the basis of voting power.

Name	Securities	Class	Voting Power
Michael Nelson*	5,040,600	Class A Membership Units	30.5%
Erick Berglund*	4,040,700	Class A Membership Units	24.5%

Michael Nelson also owns 360,000 Class B Membership Units and Erick Berglund also owns 245,000 Class B Membership Units, which do not have voting power, except in extraordinary matters.

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.

Since inception, the Company has financed its operations primarily through advances from related parties and through capital raises. As of December 31, 2019, the Company had a members' equity of $258,314. During the years ended December 31, 2019 and 2018, the Company incurred net losses of $354,179 and $414,112, respectively, and had current assets in excess of current liabilities by $68,541 as of December 31, 2019. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

The COVID-19 pandemic has resulted in the disruption of capital raising activity for the Company, including the delay or loss of investment which has negatively impacted both our short-term and long-term liquidity. The COVID-19 pandemic has also caused a delay in certain of our operations. While the ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change, we have since raised some capital that was delayed by the COVID-19 pandemic. We do not yet know

the full extent of potential delays or impacts on our business, financing or other activities.

The Company has outstanding debt of $290,264, which is the principal amount outstanding under the note payable assumed by the Company pursuant to the Company's License Agreement with Allovate, LLC, described under "Transactions with Related Persons and Conflicts of Interest - Related Person Transactions – Patent License Agreement." Interest accrued on the note at the rate of 5% between December 14, 2015 and November 26, 2017. On November 27, 2017, the interest rate under the note increased to 10%. The original maturity date of the note was November 27, 2017, which was extended to December 31, 2021. The Company recognized it will need to raise additional capital in order to fund operations, meet its payment obligations and execute its business plan. There is no assurance that additional financing will be available when needed or that management will be able to obtain financing on terms acceptable to the Company and whether the Company will generate revenues, become profitable, and generate positive operating cash flow. If the Company is unable to raise sufficient additional funds on favorable terms, it will have to develop and implement a plan to further extend payables and to raise capital through the issuance of debt or equity on less favorable terms until sufficient additional capital is raised to support further operations. There can be no assurance that such a plan will be successful. If the Company is unable to obtain financing on a timely basis, the Company could be forced to sell its assets, discontinue its operations and/or pursue other strategic avenues to commercialize its technology, and its intellectual property could be impaired.

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's members and affiliated parties advance money to fund operations and various related persons and entities have provided services to the Company. As of December 31, 2019 and 2018, related party payables totaled $138 and $46,514, respectively. In addition, Allovate, LLC was issued $180,000 Series A Preferred Units in exchange for $180,000.42 in debt obligations the Company was liable for pursuant to the patent license agreement discussed below.

Office Use

The Company's principal office is located in space leased by Allovate, LLC, d/b/a Allovate Therapeutics ("Allovate"), an affiliate under common control with the Company. The company pays the value of the rent and associated utilities for the portion of the space utilized by Intrommune.

Patent License Agreement

The Company entered an exclusive license agreement with Allovate, for certain patent rights and associated technology related to the commercial development, use, and sale of products in the field of food allergen-specific immunotherapy for humans with food allergies. The agreement's effective date is on the date of the first license fee payment. The agreement obliges the Company to the following payments:

- License issue fee of $2,000,000, payable as 10% of the equity funding to the Company after raising $1,000,000 and up to $10,000,000, then 5% of equity funding to the Company on the next $20,000,000 raised.

- Assumption of a $500,000 note payable incurred by Allovate in acquiring some of the licensed patent rights. Interest accrued on the note at the rate of 5% between December 14, 2015 and November 26, 2017. On November 27, 2017, the interest rate under the note increased to 10%. The original maturity date of the note was November 27, 2017, which was extended to December 31, 2021. As of June 15, 2020, the outstanding principal amount under the Note is $290,264.

- License maintenance fees of $100,000 at the first anniversary of the effective date of the agreement and increasing by $100,000 annually thereafter, payable on each succeeding anniversary until the Company is commercially selling a produced licensed under the agreement.

- Milestone payments upon achievement of various regulatory approvals and funding goals, including a $25,000,000 milestone payment upon receipt of regulatory approval to sell a product licensed under the agreement.

- Royalty payments on net sales (as defined in the agreement).

- Sublicense fees on any sublicense fees and royalties received by the Company.

The royalty payments and sublicense fees are subject to a combined minimum of $500,000 from the first calendar year of commercial sales of a product under the agreement.

Certain patent costs are to be obligations of the Company, and the Company is required to reimburse Allovate for any such patent costs incurred.

On December 31, 2017 and as of May 1, 2019, the Company and Allovate agreed to amendments to the agreement, with amendments including:

- Decreasing the license issue fee to $20 due upon the Company receiving equity financing of at least $10,000, which is required to occur by December 31, 2018.

- Increasing the interest rate of the $500,000 note payable assumed by the Company to 10%, effective November 27, 2017.
- Deferring a $500,000 milestone payment until the Company has raised aggregate gross equity financing of $20,000,000.

Conflicts of Interest

To the best of our knowledge the Company has not engaged in any transactions or relationships, which may give rise to a conflict of interest with the Company, its operations or its security holders.

OTHER INFORMATION

The Company has not failed to comply with the ongoing reporting requirements of Regulation CF § 227.202 in the past.

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.

I, Michael Nelson, Principal Executive Officer, Principal Financial Officer, and Principal Accounting Officer of the issuer, certify that the financial statements of the issuer included in this Form are true and complete in all material respects.

/s/ Michael Nelson
Name: Michael Nelson
Title: Principal Executive Officer, Principal Financial Officer, Principal Accounting Officer, Managing Member
Date: June 15, 2020

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.

/s/ Michael Nelson
Name: Michael Nelson
Title: Principal Executive Officer, Principal Financial Officer, Principal Accounting Officer, Managing Member
Date: June 15, 2020

/s/ Erick Berglund
Name: Erick Berglund
Title: Managing Member
Date: June 15, 2020

EXHIBITS

Exhibit A Financial Statements

ZENII, LLC
d/b/a Intrommune Therapeutics
A New York Limited Liability Company

Financial Statements (Unaudited)
December 31, 2019 and 2018

ZENII, LLC

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ZENII, LLC
BALANCE SHEETS (UNAUDITED)
As of December 31, 2019 and 2018

		2019		2018
ASSETS				
Current Assets:				
Cash and cash equivalents	$	154,906		25,015
Insurance receivable		-		1,499
Subscription receivable		96,100		-
Prepaid expense		-		16,535
Total Current Assets		251,006		43,049
Intangible Asset-License		500,000		500,000
TOTAL ASSETS	$	751,006	$	543,049
LIABILITIES AND MEMBERS' EQUITY (DEFICIT)				
Liabilities:				
Current Liabilities:				
Accounts payable	$	90,667		97,613
Accrued expenses		91,660		126,661
Due to related parties		138		46,514
Other Current Liabilities:				
Note Payable		-		145,454
Interest		-		38,731
Deferred Subscription		-		25,000
Total Other Current Liabilities		-		209,185
Total Current Liabilities		182,465		479,973
Long-Term Liabilities:				
Interest Payable		19,962		-
Long term debt		290,264		290,264
Total Long-Term Liabilities		310,227		290,264
Total Liabilities		492,692		770,237
Members' Equity:				
Subscription Equity		1,228,588		379,945
Accumulated Deficit		(970,274)		(607,134)
Total Members' Equity		258,314		(227,189)
TOTAL LIABILITIES AND MEMBERS' EQUITY (DEFICIT)	$	751,006	$	543,048

ZENII, LLC
STATEMENTS OF OPERATIONS (UNAUDITED)
For the years ended December 31, 2019 and 2018

	2019	2018
Net revenues	$ -	$ -
Operating Expenses:		
General & administrative	342,504	276,569
Research & development	11,674	137,542
Total Operating Expenses	354,179	414,112
Loss from operations	(354,179)	(414,112)
Provision for income taxes	-	-
Net loss	$ (354,179)	$ (414,112)

ZENII, LLC
STATEMENTS OF CHANGES IN MEMBERS' EQUITY (DEFICIT) (UNAUDITED)
For the years ended December 31, 2019 and 2018

	Number of Units	Amount	Capital Contributions Receivable	Accumulated Deficit	Total Members' Equity
Balance at January 1, 2018	15,00,000	$ 755	$ -	$ (193,023)	$ (192,268)
Issuance of membership units	683,190	$ 379,190	$ -	$ -	$ 379,190
Net loss	-	-	-	(414,112)	(414,112)
Balance at December 31, 2018	15,683,190	$ 379,945	$ -	$ (607,134)	$ (227,189)
Issuance of membership units	1,598,715	$ 752,543	$ 96,100	$ -	$ 848,643
Net loss	-	-	-	(354,179)	(354,179)
Net Loss Adjustments	-	-	-	(8,961)	(8,961)
Balance at December 31, 2019	17,281,905	$ 1,132,488	$ 96,100	$ (970,274)	$ 258,314

ZENII, LLC
STATEMENTS OF CASH FLOWS (UNAUDITED)
For the years ended December 31, 2019 and 2018

	2019	2018
Cash Flows From Operating Activities		
Net Loss	(354,179)	(414,112)
Adjustments to reconcile net loss to net cash used in operating activities:		
Changes in operating assets and liabilities:		
Increase/(Decrease) in prepaid expense	-	(3,368)
(Increase)/Decrease in accounts payable	(6,946)	97,000
(Increase)/Decrease in accrued expenses	(35,001)	(7,847)
(Increase)/Decrease in due to related party	(46,376)	-
Increase/(Decrease) in refund receivable	1,499	(1,499)
Net Cash Used In Operating Activities	(441,004)	(329,825)
Cash Flows From Investing Activities		
Intangible Assets	-	(500,000)
Cash Flows From Financing Activities		
(Increase)/Decrease in subscription receivable	(96,100)	-
Increase/(Decrease) in note payable	(145,454)	145,454
Increase/(Decrease) in interest payable	(18,769)	38,731
Increase/(Decrease) in deferred subscription	(25,000)	25,000
Payments for sale of membership units	856,216	379,190
Decrease in related party payables	-	(24,000)
Long term debt	-	290,264
Net Cash Provided by Financing Activities	570,893	854,640
Net Change In Cash	129,890	24,815
Cash at Beginning of Period	25,016	200
Cash at End of Period	$ 154,906	$ 25,016

NOTE 1: NATURE OF OPERATIONS

ZENII, LLC, doing business as Intrommune Therapeutics (the "Company"), is a limited liability company organized December 31, 2013 under the laws of the State of New York. The Company is a biotechnology company developing treatments for food allergies delivered via an oral mucosal immunotherapy platform.

NOTE 2: SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accounting and reporting policies of the Company conform to accounting principles generally accepted in the United States of America (GAAP). The Company adopted the calendar year as its basis of reporting.

Use of Estimates

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

Cash Equivalents and Concentration of Cash Balance

The Company considers all highly liquid securities with an original maturity of less than three months to be cash equivalents. The Company's cash and cash equivalents in bank deposit accounts, at times, may exceed federally insured limits. As of December 31, 2019 and 2018, the Company's cash and cash equivalents did not exceed FDIC insured limits.

Fair Value of Financial Instruments

Financial Accounting Standards Board ("FASB") guidance specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement). The three levels of the fair value hierarchy are as follows:

Level 1 - Unadjusted quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 1 primarily consists of financial instruments whose value is based on quoted market prices such as exchange- traded instruments and listed equities.

Level 2 - Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly (e.g., quoted prices of similar assets or liabilities inactive markets, or quoted prices for identical or similar assets or liabilities in markets that are not active).

Level 3 - Unobservable inputs for the asset or liability. Financial instruments are considered Level 3 when their fair values are determined using pricing models, discounted cash flows or similar techniques and at least one significant model assumption or input is unobservable.

The carrying amounts reported in the balance sheets approximate their fair value.

Revenue Recognition

The Company recognizes revenue when: (1) persuasive evidence exists of an arrangement with the customer reflecting the terms and conditions under which products or services will be provided; (2) delivery has occurred or services have been provided; (3) the fee is fixed or determinable; and (4) collection is reasonably assured. No revenues have been earned or recognized to date.

Organizational Costs

In accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 720, organizational costs, including accounting fees, legal fees, and costs of incorporation, are expensed as incurred.

Research and Development

Research and development costs are expensed as incurred. Total expense related to research and development was $11,674 and $137,542 for the years ended December 31, 2019 and 2018, respectively.

Income Taxes

The Company elected to be taxed as a C-corporation effective in 2014.

The Company uses the liability method of accounting for income taxes as set forth in ASC 740, Income Taxes. Under the liability method, deferred taxes are determined based on the temporary differences between the financial statement and tax basis of assets and liabilities using tax rates expected to be in effect during the years in which the basis differences reverse. A valuation allowance is recorded when it is unlikely that the deferred tax assets will be realized.

The Company assesses its income tax positions and records tax benefits for all years subject to examination based upon its evaluation of the facts, circumstances and information available at the reporting date. In accordance with ASC 740-10, for those tax positions where there is a greater than 50% likelihood that a tax benefit will be sustained, our policy is to record the largest amount of tax benefit that is more likely than not to be realized upon ultimate settlement with a taxing authority

that has full knowledge of all relevant information. For those income tax positions where there is less than 50% likelihood that a tax benefit will be sustained, no tax benefit will be recognized in the financial statements. The Company has determined that there are no material uncertain tax positions.

The Company accounts for income taxes with the recognition of estimated income taxes payable or refundable on income tax returns for the current period and for the estimated future tax effect attributable to temporary differences and carryforwards. Measurement of deferred income items is based on enacted tax laws including tax rates, with the measurement of deferred income tax assets being reduced by available tax benefits not expected to be realized in the immediate future. The Company's tax filings to date have not included its full financial activity, but will be amended to account for expenses and resulting tax losses to date. Upon amendment, the Company expects to have net operating loss carryforwards of $970,274 and $607,134 as of December 31, 2019 and 2018, respectively, which will result in net deferred tax assets of $280,409 and $175,462 as of December 31, 2019 and 2018, respectively. Deferred tax assets are determined using the Company's effective blended Federal and state tax rate of 28.9%. Due to uncertainty as to the Company's ability to generate sufficient taxable income in the future to utilize the net operating loss carryforwards before they begin to expire in 2035, the Company has recorded a full valuation allowance to reduce the net deferred tax asset to zero.

The Company files U.S. federal and state income tax returns. All previous tax returns have been filed. All tax periods since inception remain open to examination by the taxing jurisdictions to which the Company is subject.

Risks and Uncertainties

As of December 31, 2019, the Company has not commenced planned principal operations. Once the Company commences its planned full-scale principal operations, it will incur significant additional expenses. The Company is dependent upon additional capital resources for the commencement of its planned principal operations and is subject to significant risks and uncertainties; including failing to secure funding to operationalize the Company's full-scale operations or failing to profitably operate the business.

NOTE 3: GOING CONCERN

Since inception, the Company has financed its operations primarily through advances from related parties and through capital raises. As of December 31, 2019, the Company had a members' equity of $258,314. During the years ended December 31, 2019 and 2018, the Company incurred net losses of $354,179 and $414,112, respectively, and had current assets in excess of current liabilities by $68,541 as of December 31, 2019. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

The COVID-19 pandemic has resulted in the disruption of capital raising activity for the Company, including the delay or loss of investment which has negatively impacted both our short-term and long-term liquidity. The COVID-19 pandemic has also caused a delay in certain operations. While the ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change, we have since raised some capital that was delayed by the COVID-19 pandemic. We do not yet know the full extent of potential delays or impacts on our business, financing or other activities.

The Company recognized it will need to raise additional capital in order to fund operations, meet its payment obligations and execute its business plan. There is no assurance that additional financing will be available when needed or that management will be able to obtain financing on terms acceptable to the Company and whether the Company will generate revenues, become profitable, and generate positive operating cash flow. If the Company is unable to raise sufficient additional funds on favorable terms, it will have to develop and implement a plan to further extend payables and to raise capital through the issuance of debt or equity on less favorable terms until sufficient additional capital is raised to support further operations. There can be no assurance that such a plan will be successful. If the Company is unable to obtain financing on a timely basis, the Company could be forced to sell its assets, discontinue its operations and/or pursue other strategic avenues to commercialize its technology, and its intellectual property could be impaired.

The accompanying financial statements have been prepared in conformity with U.S. GAAP, which contemplates continuation of the Company as a going concern and the realization of assets and the satisfaction of liabilities in the normal course of business. The carrying amounts of assets and liabilities presented in the financial statements do not necessarily represent realizable or settlement values. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

NOTE 4: MEMBERS' EQUITY (DEFICIT)

The Company denotes its ownership interests in membership units, and has authorized three classes of membership units: Class A Units, Class B Units and Series A Preferred Units. The Company has 15,154,555 and 15,154,555 (adjusted for a 1:150 Class A unit split) Class A Units issued and outstanding as of December 31, 2019 and 2018, respectively. The Company has 1,046,500 and 304,000 Class B Units issued and outstanding as of December 31, 2019 and 2018, respectively. The Company has 1,080,850 and 224,635 Series A Preferred Units as of December 31, 2019 and 2018, respectively. The Company has 203,462 and 0.0 warrants for Series A Preferred Units as of December 31, 2019 and 2018, respectively. The Series A Preferred and Class A Units are entitled to priority on distributions or if and upon liquidation with respect to their capital account balances. After first satisfying Series A Preferred Units capital account balances, and second Class A Units capital account balances, distributions, including those if and upon liquidation, are allocated to all unitholders ratably.

The members of the Company contributed $848,643 and $379,190 of the capital to the Company during the years ended December 31, 2019 and 2018, respectively. No distributions were made during those years.

The debts, obligations, and liabilities of the Company, whether arising in contract, tort, or otherwise, are solely the debts, obligations, and liabilities of the Company, and no member of the Company is obligated personally for any such debt, obligation, or liability.

NOTE 5: COMMITMENTS, CONTINGENCIES AND CONCENTRATIONS

See the patent license agreement discussed in Note 6.

The Company may be subject to pending legal proceedings and regulatory actions in the ordinary course of business. The results of such proceedings cannot be predicted with certainty, but the Company does not anticipate that the final outcome, if any, arising out of any such matter will have a material adverse effect on its business, financial condition or results of operations.

NOTE 6: RELATED PARTIES

Related Party Transactions

From time to time, the Company's members and affiliated parties advance money to fund operations and various related persons and entities have provided services to the Company. As of December 31, 2019 and 2018, related party payables totaled $138 and $46,514, respectively. In addition, as of December 31, 2019, Allovate, LLC was issued a total of 180,000 Series A Preferred Units and 15,000 warrants for Series A preferred Units, in exchange for $180,000.42 in debt obligations the Company was liable for pursuant to the patent license agreement discussed below.

Office Use

The Company's principal office is located in space leased by Allovate, LLC, d/b/a Allovate Therapeutics ("Allovate"), an affiliate under common control with the Company. The Company pays the value of the rent and associated utilities for the portion of the space utilized by Intrommune.

Patent License Agreement

The Company entered an exclusive license agreement with Allovate, for certain patent rights and associated technology related to the commercial development, use, and sale of products in the field of food allergen-specific immunotherapy for humans with food allergies. The agreement's effective date is on the date of the first license fee payment. The agreement obliges the Company to the following payments:

- License issue fee of $2,000,000, payable as 10% of the equity funding to the Company after raising $1,000,000 and up to $10,000,000, then 5% of equity funding to the Company on the next $20,000,000 raised, and the assumption of a $500,000 note payable bearing interest at 5% between December 14, 2015 and November 26, 2017. On November 27, 2017, the interest rate under the note increased to 10%.

- License maintenance fees of $100,000 at the first anniversary of the effective date of the agreement and increasing by $100,000 annually thereafter, payable on each succeeding anniversary until the Company is commercially selling a produced licensed under the agreement.
- Milestone payments upon achievement of various regulatory approvals and funding goals, including a $25,000,000 milestone payment upon receipt of regulatory approval to sell a product licensed under the agreement.
- Royalty payments on net sales (as defined in the agreement).
- Sublicense fees on any sublicense fees and royalties received by the Company.
- The royalty payments and sublicense fees are subject to a combined minimum of $500,000 from the first calendar year of commercial sales of a product under the agreement.
- Certain patent costs are to be obligations of the Company, and the Company is required to reimburse Allovate for any such patent costs incurred.

On December 31, 2017 and as of May 1, 2019, the Company and Allovate agreed to amendments to the agreement, with amendments including:

- Decreasing the license issue fee to $20 due upon the Company receiving equity financing of at least $10,000, which is required to occur by December 31, 2018.
- Increasing the interest rate of the $500,000 note payable to be assumed by the Company to 10%, effective November 27, 2017.
- Defers a $500,000 milestone payment until the Company has raised aggregate gross equity financing of $20,000,000.

The Company has agreed to assume a $500,000 note payable issued by Allovate, LLC. Interest accrued on the note at the rate of 5% between December 14, 2015 and November 26, 2017. On November 27, 2017, the interest rate under the note increased to 10%. As of November 29, 2018, the maturity date of the note payable was extended to December 31, 2021. As of June 15, 2020, the outstanding principal amount under the note is $290,264.

NOTE 7: RECENT ACCOUNTING PRONOUNCEMENTS

In May 2014, the FASB issued ASU 2014-09, "Revenue from Contracts with Customers" (Topic 606). This ASU supersedes the previous revenue recognition requirements in ASC Topic 605—Revenue Recognition and most industry-specific guidance throughout the ASC. The core principle within this ASU is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration expected to be received for those goods or services. In August 2015, the FASB issued ASU 2015-14, "Revenue from Contracts with Customers", which deferred the effective date for ASU 2014-09 by one year to fiscal years beginning after December 15, 2017, while providing the option to early adopt for fiscal years beginning after December 15, 2016. Transition methods under ASU 2014-09 must be through either (i) retrospective application to each prior reporting period presented, or (ii) retrospective application with a cumulative effect adjustment at the date of initial application. We are continuing to evaluate

the impact of this new standard on our financial reporting and disclosures, including but not limited to a review of accounting policies, internal controls and processes.

In June 2014, the FASB issued Accounting Standards Update No. 2014-12, "Compensation - Stock Compensation (Topic 718): Accounting for Share-Based Payments when the terms of an award provide that a performance target could be achieved after the requisite service period," ("ASU 2014-12"). Current U.S. GAAP does not contain explicit guidance on whether to treat a performance target that could be achieved after the requisite service period as a performance condition that affects vesting or as a nonvesting condition that affects the grant-date fair value of an award. The new guidance requires that a performance target that affects vesting and that could be achieved after the requisite service period is treated as a performance condition. As such, the performance target should not be reflected in estimating the grant-date fair value of the award. The updated guidance will be effective for annual reporting periods beginning after December 15, 2015, including interim periods within that reporting period. The adoption of this ASU did not have any impact on the Company's consolidated financial position, liquidity, or results of operations.

In February 2016, the FASB issued ASU 2016-02, "Leases" (Topic 842). This ASU requires a lessee to recognize a right-of-use asset and a lease liability under most operating leases in its balance sheet. The ASU is effective for annual and interim periods beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. We are continuing to evaluate the impact of this new standard on our financial reporting and disclosures.

In July 2014, the FASB issued the ASU No. 2015-11 on "Inventory (Topic 330): Simplifying the Measurement of Inventory", which proposed that inventory should be measured at the lower of cost and the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. These amendments are based on existing guidance that requires measuring inventory at the lower of cost or market to consider the replacement cost of inventory less an approximately normal profit margin along with net value in determining the market value. It is effective for reporting periods beginning after December 15, 2016. Management is assessing the impact of this pronouncement on our financial statements.

In August 2016, the FASB issued ASU 2016-15, "Statement of Cash Flows" (Topic 230). This ASU is intended to reduce diversity in practice in how certain transactions are classified in the statement of cash flows. This ASU is effective for financial statements issued for fiscal years beginning after December 15, 2017. We do not believe the adoption of ASU 2016-15 will have a material impact on our financial position, results of operations or cash flows.

Management does not believe that any other recently issued, but not yet effective, accounting standards could have a material effect on the accompanying financial statements. As new accounting pronouncements are issued, we will adopt those that are applicable under the circumstances.

NOTE 8: SUBSEQUENT EVENTS

Management's Evaluation

As of May 13, 2020, an additional 275,000 Series A Preferred Units were issued. Management has evaluated subsequent events through June 15, 2020, the date the financial statements were available to be issued. Based on this evaluation, no additional material events were identified which require adjustment or disclosure in these financial statements.