# Offering Statement for ZENII, LLC ("Intrommune Therapeutics")

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The information contained herein includes forward-looking statements. These statements relate to future events or to future financial performance, and involve known and unknown risks, uncertainties, and other factors, that may cause actual results to be materially different from any future results, levels of activity, performance, or achievements expressed or implied by these forward-looking statements. You should not place undue reliance on forward-looking statements since they involve known and unknown risks, uncertainties, and other factors, which are, in some cases, beyond the company's control and which could, and likely will, materially affect actual results, levels of activity, performance, or achievements. Any forward-looking statement reflects the current views with respect to future events and is subject to these and other risks, uncertainties, and assumptions relating to operations, results of operations, growth strategy, and liquidity. No obligation exists to publicly update or revise these forward-looking statements for any reason, or to update the reasons actual results could differ materially from

those anticipated in these forward-looking statements, even if new information becomes available in the future.

## The Company

1. What is the name of the issuer? ZENII, LLC

# **Eligibility**

- 2. The following are true for ZENII, LLC:
  - Organized under, and subject to, the laws of a State or territory of the United States or the District of Columbia.
  - Not subject to the requirement to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934.
  - Not an investment company registered or required to be registered under the Investment Company Act of 1940.
  - Not ineligible to rely on this exemption under Section 4(a)(6) of the Securities Act as a result of a disqualification specified in Rule 503(a) of Regulation Crowdfunding. (For more information about these disqualifications, see Question 30 of this Question and Answer format).
  - Has filed with the Commission and provided to investors, to the extent required, the ongoing annual reports required by Regulation Crowdfunding during the two years immediately preceding the filing of this offering statement (or for such shorter period that the issuer was required to file such reports).
  - Not a development stage company that (a) has no specific business plan or (b) has indicated that its business plan is to engage in a merger or acquisition with an unidentified company or companies.
- 3. Has the issuer or any of its predecessors previously failed to comply with the ongoing reporting requirements of Rule 202 of Regulation Crowdfunding?

  No.

# **Directors, Officers and Promoters of the Company**

4. The following individuals (or entities) represent the company as a director, officer or promoter of the offering:

#### **Michael Nelson**

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 Therapuetics since December 2013. Mr. Nelson has served the Chief Financial Officer of Immunovent, LLC, a company developing a novel allergy diagnostic, since February 2013, and as Chief Financial Officer of Allovate, LLC, from which Intrommune is licensing its food allergy oral mucosal immunotherapy platform, since February 2012. Mr. Nelson is a periodic advisor to Westwood Capital, LLC with over 20 years of investment banking, legal, management and investing

experience. 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 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**

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. Since August 2013, Dr. Berglund has served as the Chief Scientific Officer of Intrommune Therapuetics. From February 2013 to October 2015, Dr. Berglund served as the Chief Executive Officer of Immunovent, LLC, a company developing a novel allergy diagnostic, and since February 2012 he has served as the Chief Executive Officer of Allovate, LLC, from which Intrommune is licensing its food allergy oral mucosal immunotherapy platform. From July 2011 until August 2013, Dr. Berglund worked for H4B, a stand-alone medical communications firm. 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 cellspecific gene expression. As a co-founder and CSO 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.

## **Anthony Robinson**

Mr. Robinson has spent 25 years in the life sciences including: healthcare, medical, pharmaceutical, biotech, and consulting services executing clinical and business operations, product development, product commercialization, sales, business development, finance, and corporate development. Since January 2015, Mr. Robinson has served as the Chief Operating Officer of Intrommune Therapeutics. Prior to establishing Barclay Consulting LLC in 2014, Mr. Robinson worked within Research and Development at Shire, 2006-2014 and Covance Inc., 2001-2006. Mr. Robinson has a Master's in Science from MCP Hahnemann (Drexel University), a Master's in Business Administration from Pennsylvania State University, and a Bachelor's in Science from Cornell University.

## **Principal Security Holders**

5. Provide the name and ownership level of each person, as of the most recent practicable date, who is the beneficial owner of 20 percent or more of the issuer's outstanding voting equity securities, calculated on the basis of voting power. To calculate total voting power, include all securities for which the person directly or indirectly has or shares the voting power, which includes the power to vote or to direct the voting of such securities. If the person has the right to acquire voting power of such securities within 60 days, including through the exercise of any option, warrant or right, the conversion of a security, or other arrangement, or if securities are held by a member of the family, through corporations or partnerships, or otherwise in a manner that would allow a person to direct or control the voting of the securities (or share in such direction or control — as, for example, a cotrustee) they should be included as being "beneficially owned." You should include an explanation of these circumstances in a footnote to the "Number of and Class of Securities Now Held." To calculate outstanding voting equity securities, assume all outstanding options are exercised and all outstanding convertible securities converted.

#### **Michael Nelson**

Securities: 5,040,600

Class: Class A Membership Units

Voting Power: 33.6%

**Erick Berglund** 

Securities: 4,040,700

Class: Class A Membership Units

Voting Power: 26.9%

# **Business and Anticipated Business Plan**

6. Describe in detail the business of the issuer and the anticipated business plan of the issuer.

Intrommune Therapeutics is developing a novel therapeutic platform for treating food allergy. The therapy works simultaneously as users brush their teeth with a specialized toothpaste, called oral mucosal immunotherapy (OMIT). The lead product candidate is INT-301 for peanut allergy, which addresses an unmet medical need for millions of people worldwide (including upwards of 3 million Americans) with a potentially deadly allergy to peanut. INT-301 will allow users to seamlessly integrate disease-modifying treatment for peanut allergy into their everyday routine. With long-term consistent use of the product, it is expected that people with peanut allergy will fundamentally decrease their sensitivity to peanut and be able to live free from the constant fear of serious allergic reactions. Intrommune is pursuing a straight FDA-approval pathway for INT-301 for peanut allergy, followed by product development for several other key food allergies. Once approved by the FDA, it is expected that insurance payors will cover the cost of therapy to food allergy sufferers. During the development phase, several significant value inflections are expected, opening the door to exits and monetizations that are common in the pharma field, including co-development and partnership, acquisition, and IPO.

## **Risk Factors**

A crowdfunding investment involves risk. You should not invest any funds in this offering unless you can afford to lose your entire investment.

In making an investment decision, investors must rely on their own examination of the issuer and the terms of the offering, including the merits and risks involved. These securities have not been recommended or approved by any federal or state securities commission or regulatory authority. Furthermore, these authorities have not passed upon the accuracy or adequacy of this document.

The U.S. Securities and Exchange Commission does not pass upon the merits of any securities offered or the terms of the offering, nor does it pass upon the accuracy or completeness of any offering document or literature.

These securities are offered under an exemption from registration; however, the U.S. Securities and Exchange Commission has not made an independent determination that these securities are exempt from registration.

#### 7. Material factors that make an investment in ZENII, LLC speculative or risky:

- 1. 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.
- 2. 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, 2017, we had an accumulated deficit of approximately \$193,023. Our principal intellectual property is licensed from an affiliated company, Allovate, LLC, as described under "Related Party Transactions." The license agreement with Allovate 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. Further, we are required to annually spend not less than \$4,000,000 for the development of licensed products during the first five years of the agreement. 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.
- 3. 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.
- 4. 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.
- 5. 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.
- 6. 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.
- 7. 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.
- 8. If we are not able to retain qualified management and scientific 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 scientific and management personnel. These members include Michael Nelson, Erick Berglund, PhD and Anthony Robinson. 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 management and scientific personnel. We may be unable to retain our current personnel or attract or integrate other qualified management and scientific personnel in the future.
- 9. 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.
- 10. 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.
- 11. 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.
- 12. 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.
- 13. 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.
- 14. 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.
- 15. 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.
- 16. 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.
- 17. 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.
- 18. 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.
- 19. 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.

- 20. 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.
- 21. 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.
- 22. 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.
- 23. 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.
- 24. 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 inlicensing new product candidates.
- 25. 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.
- 26. 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.
- 27. 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.
- 28. 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.
- 29. 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.
- 30. You may not be able to sell or transfer your Class A Units. You should not plan on being able to readily transfer and/or resell your Class A Units. Currently there is no market or liquidity for the Class A Units and the Company does not have any plans to list the Class A Units or any other equity securities on an exchange or other secondary market. The Class A Units have not been registered under the Securities Act of 1933, as amended, nor is any such registration contemplated. The sale or transfer of Class A 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 Class A Units is suitable only for individuals and entities that have no need for liquidity with respect to their investment.
- 31. 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.
- 32. 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. Information provided concerning this Offering and the Company's business may contain forward-looking statements, which can be identified by, among other things, the use of forward-looking language, such as the words "plans," "intends," "believes," "expects," "anticipates," "estimates," "projects," "potential," "may," "will," "would," "could," "should," "seeks," or "scheduled to," or other similar words, or by discussion of strategy or intentions. Such forward looking statements reflect management's current view with respect to future events and the Company's performance. Such forwardlooking statements may include projections with respect to product development, market size and acceptance, revenues and earnings, marketing and sales strategies, and business operations. The Company operates in a highly competitive business environment. The Company's business is and will continue to be affected by government regulation, economic, political and social conditions, response of the medical community to our products, technological developments and, particularly in view of new technologies, the ability to protect intellectual property rights. The Company's actual results could differ materially from management's expectations because of changes in such factors. Other factors and risks could also cause actual results to differ from those contained in forward-looking statements. Due to such uncertainties and the risk factors set forth herein, prospective investors are cautioned not to place undue reliance upon such forward-looking statements.

# **The Offering**

ZENII, LLC ("Company") is offering securities under both Regulation D, through Livingston Securities, LLC ("Livingston") and Regulation CF, through Netcapital Funding Portal Inc. ("Portal"). Livingston is a registered broker-dealer, and member FINRA/SIPC. Livingston will receive cash compensation equal to 4.9% of the value of the securities sold through Regulation D. Portal is a FINRA/SEC registered funding portal and will receive cash compensation equal to 4.9% of the value of the securities sold through Regulation CF. Investments made under both Regulation D and Regulation CF involve a high degree of risk and those investors who cannot afford to lose their entire investment should not invest.

This offering is considered a side-by-side offering, meaning that the Company is raising capital under two offering types. The Company plans to raise between \$10,000 and \$2,000,100 through concurrent offerings under Regulation CF and Regulation D – Rule 506(c). Specifically, if we reach the target offering amount of \$10,000, we may conduct the first of multiple or rolling closings of the offering early if we provide notice about the new offering deadline at least five business days prior to such new offering deadline (absent a material change that would require an extension of the offering and reconfirmation of the investment commitment). Oversubscriptions will be allocated on a first come, first served basis. Changes to the offering, material or otherwise, occurring after a closing, will only impact investments which have yet to be closed.

In the event The Company fails to reach the combined offering target of \$10,000, any investments made under either offering will be cancelled and the investment funds will be returned to the investor.

The Company may raise up to \$1,070,000 from non-accredited investors under Regulation CF.

Accredited investors who have proved their accreditation status to Portal, will automatically invest under the Regulation D - Rule 506(c) offering type. All other investors will invest under the Regulation CF offering type. An accredited investor who proves their accreditation status with the Portal prior to 48 hours of the offering closing, can authorize their investment to be withdrawn from the Regulation CF offering and automatically reinvested in the Regulation D offering. You must be an accredited investor to invest under Regulation D.

#### 8. What is the purpose of this offering?

Intrommune will allocate proceeds towards Research and Development, specifically pre-clinical and clinical development and investigations, Chemistry, Manufacturing and Controls, Stability Testing and FDA regulatory requirements such as pre-IND interactions and IND filings.

#### 9. How does the issuer intend to use the proceeds of this offering?

	If Target Offering Amount Sold	If Maximum Amount Sold
Total Proceeds	\$10,000	\$2,000,100
Less: Offering Expenses	\$490	\$98,005
Net Proceeds	\$9,510	\$1,902,095
Research and Development	\$9,510	\$1,090,000
Chemistry, Manufacturing and Controls	\$0	\$250,000
Regulatory	\$0	\$50,000
Operating costs	\$0	\$512,096
Total Use of Net Proceeds	\$9,510	\$1,902,096

#### 10. How will the issuer complete the transaction and deliver securities to the investors?

In entering into an agreement on the Netcapital Funding Portal to purchase securities, both investors and ZENII, LLC must agree that a transfer agent, which keeps records of our outstanding Class A Membership Units (the "Securities"), will issue digital Securities in the investor's name (a paper certificate will not be printed). Similar to other online investment accounts, the transfer agent will give investors access to a web site to see the number of Securities that they own in our company. These Securities will be issued to investors after the deadline date for investing has passed, as long as the targeted offering amount has been reached. The transfer agent will record the issuance when we have received the purchase proceeds from the escrow agent who is holding your investment commitment.

#### 11. How can an investor cancel an investment commitment?

You may cancel an investment commitment for any reason until 48 hours prior to the deadline identified in the offering by logging in to your account with Netcapital, browsing to the Investments screen, and clicking to cancel your investment commitment. Netcapital will notify investors when the target offering amount has been met. If the issuer reaches the target offering amount prior to the deadline identified in the offering materials, it may close the offering early if it provides notice about the new offering deadline at least five business days prior to such new offering deadline (absent a material change that would require an extension of the offering and reconfirmation of the investment commitment). If an investor does not cancel an investment commitment before the 48-hour period prior to the offering deadline, the funds will be released to the issuer upon closing of the offering and the investor will receive securities in exchange for his or her investment. If an investor does not reconfirm his or her investment commitment after a material change is made to the offering, the investor's investment commitment will be cancelled and the committed funds will be returned.

#### 12. Can the Company perform multiple closings or rolling closings for the offering?

If we reach the target offering amount prior to the offering deadline, we may conduct the first of multiple closings of the offering early, if we provide notice about the new offering deadline at least five business days prior (absent a material change that would require an extension of the offering and reconfirmation of the investment commitment). Thereafter, we may conduct additional closings until the offering deadline. We will issue Securities in connection with each closing.

Oversubscriptions will be allocated on a first come, first served basis. Changes to the offering, material or otherwise, occurring after a closing, will only impact investments which have yet to be closed.

# **Ownership and Capital Structure**

## The Offering

13. Describe the terms of the securities being offered.

We are issuing Securities at an offering price of \$1.00 per share.

14. Do the securities offered have voting rights?

The Securities are being issued with voting rights. However, so that the crowdfunding community has the opportunity to act together and cast a vote as a group when a voting matter arises, a custodian will cast your vote for you. Please refer to the custodian agreement that you sign before your purchase is complete.

15. Are there any limitations on any voting or other rights identified above?

You are giving your voting rights to the custodian, who will vote the Securities on behalf of all investors who purchased Securities on the Netcapital crowdfunding portal.

16. How may the terms of the securities being offered be modified?

We may choose to modify the terms of the securities before the offering is completed. However, if the terms are modified, and we deem it to be a material change, we need to contact you and you will be given the opportunity to reconfirm your investment. Your reconfirmation must be completed within five business days of receipt of the notice of a material change, and if you do not reconfirm, your investment will be canceled and your money will be returned to you.

#### **Restrictions on Transfer of the Securities Offered**

The securities being offered may not be transferred by any purchaser of such securities during the oneyear period beginning when the securities were issued, unless such securities are transferred:

- to the issuer:
- to an accredited investor;
- as part of an offering registered with the U.S. Securities and Exchange Commission; or
- to a member of the family of the purchaser or the equivalent, to a trust controlled by the purchaser, to a trust created for the benefit of a member of the family of the purchaser or the equivalent, or in connection with the death or divorce of the purchaser or other similar circumstance.

The term "accredited investor" means any person who comes within any of the categories set forth in Rule 501(a) of Regulation D, or who the seller reasonably believes comes within any of such categories, at the time of the sale of the securities to that person.

The term "member of the family of the purchaser or the equivalent" includes a child, stepchild, grandchild, parent, stepparent, grandparent, spouse or spousal equivalent, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law of the purchaser, and includes adoptive relationships. The term "spousal equivalent" means a cohabitant occupying a relationship generally equivalent to that of a spouse.

## **Description of Issuer's Securities**

17. What other securities or classes of securities of the issuer are outstanding? Describe the material terms of any other outstanding securities or classes of securities of the issuer.

#### **Securities**

Class of Security	Amount Authorized	Amount Outstanding		Other Rights
Class A Membership Units	17,000,100	15,000,000	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	0	0	No	After satisfying Class A Unit capital account balances, distributions, including those if and upon liquidation, are allocated to all unit holders ratably.

## **Options, Warrants and Other Rights**

None.

18. How may the rights of the securities being offered be materially limited, diluted or qualified by the rights of any other class of securities?

We currently have no convertible debt, and currently there are no warrants, options, or other convertible instruments outstanding, which if exercised, would be dilutive to the investors that purchase Class A Units in this offering.

19. Are there any differences not reflected above between the securities being offered and each other class of security of the issuer?

The Company grants to any investor that participates in this crowdfunding offering, a perpetual waiver from the provisions that limit and restrict the ability of a member to transfer units, pursuant to Article 2.2 of the Company's Operating Agreement. Existing members that own Class A Membership Units are restricted by the provisions of Article 2.2.

20. How could the exercise of rights held by the principal owners identified in Question 5 above affect the purchasers of Securities being offered?

ZENII LLC (referred to in these risk factors as "Intrommune", "we", "us", "our" or the "Company") has two Managing Members who have exclusive control over our activities. Investors will have the status of Members holding Class A Units ("Class A Members") and will have no voice or control in the day-to-day management or conduct of the affairs of the Company. The Managing Members will have the sole and absolute right and authority to act for and on behalf of the Company in connection with all aspects of our business.

21. How are the securities being offered being valued? Include examples of methods for how such securities may be valued by the issuer in the future, including during subsequent corporate actions.

Comparables and discussions with numerous potential investors with healthcare and/or food allergy focus.

22. What are the risks to purchasers of the securities relating to minority ownership in the issuer?

The Managing Members will have the sole and absolute right and authority to act for and on behalf of the Company in connection with all aspects of our business. The Class A Members will be bound by all agreements made by the Managing Members on behalf of the Company. Accordingly, no person should invest unless he or she is willing to entrust all aspects of the management of the Company to the Managing Members and has evaluated and is satisfied with the Managing Members'

capabilities to perform such functions.

#### 23. What are the risks to purchasers associated with corporate actions including:

- additional issuances of securities,
- issuer repurchases of securities,
- a sale of the issuer or of assets of the issuer or
- transactions with related parties?

The issuance of additional membership interest units will dilute the ownership of the crowdfunding investors. As a result, if we achieve profitable operations in the future, our net income per unit will be reduced because of dilution, and the market price of our membership interest units, if there is a market price, could decline as a result of the additional issuance of securities. If we repurchase securities, so that the above risk is mitigated, and there are fewer membership units outstanding, we may not have enough cash available for marketing expenses, growth, or operating expenses to reach our goals. If we do not have enough cash to operate and grow, we anticipate the market price of our membership interest units would decline. A sale of our company or of the assets of our company may result in an entire loss of your investment. We cannot predict the market value of our company or our assets, and the proceeds of a sale may not be cash, but instead, unmarketable securities, or an assumption of liabilities. We may need to negotiate with a related party for additional capital. No assurance can be given that such funds will be available or, if available, will be on commercially reasonable terms satisfactory to us. Even if such financing is available, it may be on terms that are materially adverse to your interests with respect to dilution of book value, dividend preferences, liquidation preferences, or other terms. No assurance can be given that such funds will be available or, if available, will be on commercially reasonable terms satisfactory to us. There can be no assurance that we will be able to obtain financing if and when it is needed on terms we deem acceptable. If we are unable to obtain financing on reasonable terms we could be forced to discontinue our operations. We anticipate that any transactions with related parties will be vetted and approved by executives unaffiliated with the related parties.

#### 24. Describe the material terms of any indebtedness of the issuer:

Not applicable.

#### 25. What other exempt offerings has ZENII, LLC conducted within the past three years?

Date of Offering: 04/2017

Exemption: Section 4(a)(2)
Securities Offered: Membership Units

Amount Sold: \$2,405

Use of Proceeds: General and administrative expenses

Date of Offering: 11/2016

Exemption: Section 4(a)(2)
Securities Offered: Membership Units

Amount Sold: \$1.476

Use of Proceeds: General and administrative expenses

Date of Offering: 01/2016

Exemption: Section 4(a)(2)
Securities Offered: Membership Units

Amount Sold: \$35,577

Use of Proceeds: General and administrative expenses

- 26. Was or is the issuer or any entities controlled by or under common control with the issuer a party to any transaction since the beginning of the issuer's last fiscal year, or any currently proposed transaction, where the amount involved exceeds five percent of the aggregate amount of capital raised by the issuer in reliance on Section 4(a)(6) of the Securities Act during the preceding 12-month period, including the amount the issuer seeks to raise in the current offering, in which any of the following persons had or is to have a direct or indirect material interest:
  - 1. any director or officer of the issuer;
  - 2. any person who is, as of the most recent practicable date, the beneficial owner of 20 percent or more of the issuer's outstanding voting equity securities, calculated on the basis of voting power;
  - 3. if the issuer was incorporated or organized within the past three years, any promoter of the issuer; or
  - 4. any immediate family member of any of the foregoing persons.

No.

## **Financial Condition of the Issuer**

27. Does the issuer have an operating history?

Yes.

28. Describe the financial condition of the issuer, including, to the extent material, liquidity, capital resources and historical results of operations.

Since inception, the Company has financed its operations primarily through advances from related parties. As of December 31, 2017, the Company had a members' deficit of \$192,268. During the years ended December 31, 2017 and 2016, the Company incurred net losses of \$137,567 and \$52,833, respectively, used cash in operating activities of \$58,396 and \$12,050 during the years ended December 31, 2017 and 2016, respectively, and had current liabilities in excess of current assets by \$192,268 as of December 31, 2017. These conditions raise substantial doubt about the Company's ability to continue as a going concern. 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, 2017 and 2016, related party payables totaled \$70,514 and \$12,313, respectively. In addition, William Reisacher, MD, a related party and unitholder, serves as senior scientific advisor to the Company and accrues compensation for such services at a rate of \$1,000 per month. As of December 31, 2017 and 2016, the total accrued compensation payable to Dr. Reisacher for such services is \$24,000 and \$12,000 (included in the related party payables disclosed above), for research and development expenses of \$12,000 per year for each December 31, 2017 and 2016. For the year ended December 31, 2017, general and administrative expenses amounted to \$118,753, an increase of \$102,108 over expenses of \$16,645 for the year ended December 31, 2016. For the year ended December 31, 2017, research and development expenses amounted to \$18,814, a decrease of \$17,374 over expenses of \$36,188 for the year ended December 31, 2016.

## **Financial Information**

29. Include the financial information specified by regulation, covering the two most recently completed fiscal years or the period(s) since inception if shorter.

See attachments:

**CPA Review Report:** 

reviewletter.pdf

30. With respect to the issuer, any predecessor of the issuer, any affiliated issuer, any director, officer, general partner or managing member of the issuer, any beneficial owner of 20 percent or more of

the issuer's outstanding voting equity securities, calculated in the same form as described in Question 6 of this Question and Answer format, any promoter connected with the issuer in any capacity at the time of such sale, any person that has been or will be paid (directly or indirectly) remuneration for solicitation of purchasers in connection with such sale of securities, or any general partner, director, officer or managing member of any such solicitor, prior to May 16, 2016:

- 1. Has any such person been convicted, within 10 years (or five years, in the case of issuers, their predecessors and affiliated issuers) before the filing of this offering statement, of any felony or misdemeanor:
  - 1. in connection with the purchase or sale of any security?
  - 2. involving the making of any false filing with the Commission?
  - 3. arising out of the conduct of the business of an underwriter, broker, dealer, municipal securities dealer, investment adviser, funding portal or paid solicitor of purchasers of securities?
- 2. Is any such person subject to any order, judgment or decree of any court of competent jurisdiction, entered within five years before the filing of the information required by Section 4A(b) of the Securities Act that, at the time of filing of this offering statement, restrains or enjoins such person from engaging or continuing to engage in any conduct or practice:
  - 1. in connection with the purchase or sale of any security?;
  - 2. involving the making of any false filing with the Commission?
  - 3. arising out of the conduct of the business of an underwriter, broker, dealer, municipal securities dealer, investment adviser, funding portal or paid solicitor of purchasers of securities?
- 3. Is any such person subject to a final order of a state securities commission (or an agency or officer of a state performing like functions); a state authority that supervises or examines banks, savings associations or credit unions; a state insurance commission (or an agency or officer of a state performing like functions); an appropriate federal banking agency; the U.S. Commodity Futures Trading Commission; or the National Credit Union Administration that:
  - 1. at the time of the filing of this offering statement bars the person from:
    - 1. association with an entity regulated by such commission, authority, agency or officer?
    - 2. engaging in the business of securities, insurance or banking?
    - 3. engaging in savings association or credit union activities?
  - 2. constitutes a final order based on a violation of any law or regulation that prohibits fraudulent, manipulative or deceptive conduct and for which the order was entered within the 10-year period ending on the date of the filing of this offering statement?
- 4. Is any such person subject to an order of the Commission entered pursuant to Section 15(b) or 15B(c) of the Exchange Act or Section 203(e) or (f) of the Investment Advisers Act of 1940 that, at the time of the filing of this offering statement:
  - 1. suspends or revokes such person's registration as a broker, dealer, municipal securities dealer, investment adviser or funding portal?
  - 2. places limitations on the activities, functions or operations of such person?
  - 3. bars such person from being associated with any entity or from participating in the offering of any penny stock?

#### If Yes to any of the above, explain:

- 5. Is any such person subject to any order of the Commission entered within five years before the filing of this offering statement that, at the time of the filing of this offering statement, orders the person to cease and desist from committing or causing a violation or future violation of:
  - 1. any scienter-based anti-fraud provision of the federal securities laws, including without limitation Section 17(a)(1) of the Securities Act, Section 10(b) of the Exchange Act, Section 15(c)(1) of the Exchange Act and Section 206(1) of the Investment Advisers Act of 1940 or any other rule or regulation thereunder?
  - 2. Section 5 of the Securities Act?
- 6. Is any such person suspended or expelled from membership in, or suspended or barred from association with a member of, a registered national securities exchange or a registered

- national or affiliated securities association for any act or omission to act constituting conduct inconsistent with just and equitable principles of trade?
- 7. Has any such person filed (as a registrant or issuer), or was any such person or was any such person named as an underwriter in, any registration statement or Regulation A offering statement filed with the Commission that, within five years before the filing of this offering statement, was the subject of a refusal order, stop order, or order suspending the Regulation A exemption, or is any such person, at the time of such filing, the subject of an investigation or proceeding to determine whether a stop order or suspension order should be issued?
- 8. Is any such person subject to a United States Postal Service false representation order entered within five years before the filing of the information required by Section 4A(b) of the Securities Act, or is any such person, at the time of filing of this offering statement, subject to a temporary restraining order or preliminary injunction with respect to conduct alleged by the United States Postal Service to constitute a scheme or device for obtaining money or property through the mail by means of false representations?

ZENII, LLC answers 'NO' to all of the above questions.

## **Other Material Information**

31. In addition to the information expressly required to be included in this Form, include: any other material information presented to investors; and such further material information, if any, as may be necessary to make the required statements, in the light of the circumstances under which they are made, not misleading.

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. As of December 31, 2017, the value of the rent and associated utilities for the portion of the space utilized by Intrommune is de minimis. 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% commencing December 14, 2015 and matured November 27, 2017. • 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, the Company and Allovate agreed to an amendment 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 in 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. Various advisors to the Company have deferred payment arrangements that trigger payment upon securing \$1,000,000 of financing. The Company denotes its ownership interests in membership units, and has authorized two classes of membership units: Class A Units and Class B Units. The Company had 100,000 and 97,595 Class A Units issued and outstanding as of December 31, 2017 and 2016, respectively. No Class B Units have been issued as of December 31, 2017 or 2016. Class A Units are entitled to priority on distributions or if and upon liquidation with respect to their capital account balances. After satisfying Class A Unit capital account balances, distributions, including those if and upon liquidation, are allocated to all unit holders ratably. After the issuance of an independent accountant's review report of the Company's financial statements for the years ended December 31, 2017 and 2016, on April 9, 2018, the Company split its units 150 to 1. As of the date of this offering, 15,000,000 Class A Membership Units are outstanding. Offering Page Video Transcript: Peanut allergy, the most common food allergy in kids has tripled in the past 10 years. Families dealing with peanut allergy often live in fear and many kids report feeling isolated from their friends. Today here are no FDA approved treatments for peanut allergy. Here, at Intrommune Therapeutics we are developing a ground breaking toothpaste to treat peanut allergy - our toothpaste delivers pharmaceutical active ingredients to the mouth, which retrain the immune system. Our research predicts that over time the immune system will learn to stop attacking peanuts and allergic reactions will become less severe. Just like your regular toothpaste, ours keeps teeth clean and fights cavities. With Intrommune's simple treatment people with peanut allergy will able to live without fear. Our New York City team of experienced entrepreneurs and researchers, successfully tested the toothpaste last year and now we are begging safety and efficacy testing to seek FDA Approval. Your support will allow us to research, test and move forward with a solution so that normal is within reach for millions of peanut allergy sufferers. For information on how to invest, click here!

The following documents are being submitted as part of this offering:

Governance:

Certificate of Formation: certificateofformation.pdf
Operating Agreement: operatingagreement.pdf

**Opportunity:** 

Offering Page JPG: offeringpage.jpg
Pitch Deck: pitchdeck.pdf

# **Ongoing Reporting**

32. The issuer will file a report electronically with the Securities & Exchange Commission annually and post the report on its web site, no later than 120 days after the end of each fiscal year covered by the report:

Once posted, the annual report may be found on the issuer's web site at: www.intrommune.com

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

- the issuer is required to file reports under Section 13(a) or Section 15(d) of the Exchange Act;
- the issuer has filed at least one annual report pursuant to Regulation Crowdfunding and has fewer than 300 holders of record and has total assets that do not exceed \$10,000,000;
- the issuer has filed at least three annual reports pursuant to Regulation Crowdfunding;
- the issuer or another party repurchases all of the securities issued in reliance on Section 4(a)(6) of the Securities Act, including any payment in full of debt securities or any complete redemption of redeemable securities; or
- the issuer liquidates or dissolves its business in accordance with state law.