SENESCO TECHNOLOGIES INC Form 10-K October 13, 2006

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF

x 1934. For the fiscal year ended June 30, 2006

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

to

For the transition period from

Commission file number: 001-31326

SENESCO TECHNOLOGIES, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

303 George Street, Suite 420, New Brunswick, New Jersey

(Address of principal executive offices)

(732) 296-8400

(Registrant s telephone number, including area code)

None

(Former name, former address and former fiscal year, if changed since last report)

Securities registered under Section 12(b) of the Act:

Title of each class Common Stock, \$0.01 par value per share. Name of each exchange on which registered American Stock Exchange

Securities registered under Section 12(g) of the Act:

None.

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes X Noo

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act.

Large accelerated filer o Accelerated filer o Non-accelerated filer x

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

As of September 30, the aggregate market value of the registrant s common stock held by non-affiliates of the registrant was \$16,181,318, based on the closing sales price as reported on the American Stock Exchange on that date.

Indicate the number of shares outstanding of each of the registrant s classes of common stock, as of September 30, 2006:

84-1368850

(I.R.S. Employer Identification No.)

08901 (Zip Code)

Class Common Stock, \$0.01 par value

Number of Shares 15,487,388

The following documents are incorporated by reference into the Annual Report on Form 10-K: Portions of the registrant s definitive Proxy Statement for its 2006 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

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PART I

Item 1. Business.

Our Business

The primary business of Senesco Technologies, Inc., a Delaware corporation incorporated in 1999, and its wholly-owned subsidiary, Senesco, Inc., a New Jersey corporation incorporated in 1998, collectively referred to as Senesco, we, us or our, is to utilize our patented and patent-pending genes, primarily eucaryotic translation initiation Factor 5A, or Factor 5A, and deoxyhypusine synthase, or DHS, in human health applications to:

- Develop novel approaches to treat inflammatory and / or apoptotic, related diseases in humans;
- Develop novel approaches to treat cancer, a group of diseases in which apoptosis does not occur normally; and

Factor 5A, DHS and Lipase in agricultural applications, to enhance the quality and productivity of fruits, flowers, and vegetables and agronomic crops through the control of cell death, referred to as senescence, and growth in plants.

Human Health Applications

We believe that our gene technology could have broad applicability in the human health field, by either inhibiting or accelerating apoptosis. Inhibiting apoptosis may be useful in preventing or treating a wide range of inflammatory and ischemic diseases attributed to premature apoptosis. Accelerating apoptosis may be useful in treating certain forms of cancer.

Certain human health results to date include:

- Increasing median survival by approximately 250% in an in-vivo model of mice injected with melanoma cancer cells;
- Inducing apoptosis in both human cancer cell lines derived from tumors and in lung tumors in mice;
- Reducing the amounts of p24 and IL-8 by approximately 50 percent in an HIV-1 infected human cell line;
- Increasing the survival of mouse pancreatic islet cells isolated for transplantation;
- Inducing apoptosis of cancer cells in a human multiple myeloma cell line;
- Demonstrating that the efficacy of our technology is comparable to that of existing approved anti-inflammatory prescription drugs in reducing certain inflammatory cytokines in mice;
- Measuring VEGF reduction in mouse lung tumors as a result of treatment with our genes;
- Increasing the survival rate in a mouse sepsis model. Additionally, a broad spectrum of pro-inflammatory cytokines were down-regulated;

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• Determining the expression of our genes in both ischemic and non-ischemic human heart tissue, and correlating this expression to certain cytokines known to be involved in apoptosis; and

• Reducing cytokine induced apoptosis in human optic nerve cell lines and in human epithelial cell lines of the intestine.

Inhibiting Apoptosis

Our research to date reveals that the DHS and Factor 5A genes may regulate apoptosis in human cells. We believe that our Factor 5A technology may have potential application as a means for controlling a broad range of apoptotic diseases, both inflammatory / ischemic diseases and cancers. We are engaged in preclinical *in-vivo* and *in-vitro* research to determine the ability of Factor 5A to regulate key execution genes, inflammatory cytokines, receptors, and transcription factors, which are implicated in numerous apoptotic diseases.

We believe that down-regulation of our proprietary Factor 5A gene may have potential application as a means for controlling a broad range of diseases that are attributable to premature apoptosis, ischemia, or inflammation. Apoptotic diseases include glaucoma, heart disease, and certain inflammatory diseases such as Crohn s disease, sepsis and rheumatoid arthritis, among others. We are engaged in preclinical research on a variety of these diseases. Using small inhibitory RNAs, or siRNAs, against the apoptosis isoform of Factor 5A to inhibit its expression, we have reduced pro-inflammatory cytokine formation and formation of receptors for liposolysaccharide, or LPS, interferon gamma and TNF-alpha. *In-vitro* experiments have shown that siRNAs against Factor 5A protected human lamina cribrosa (optic nerve) and colon epithelial cells from TNF alpha induced apoptosis. We have also determined that inhibiting the apoptosis isoform of Factor 5A down-regulates the transcription factors NFkB and JAK1 and decreases the inflammatory cytokines formed through the NFkB and JAK/STAT pathways. Additionally, we have shown in a mouse study that our siRNA is comparable to a steroid and to a prescription anti-TNF drug in its ability to reduce cytokine response to LPS. *In-vivo* mouse studies have shown that the siRNA against Factor 5A (i) protects thymocyte cells from apoptosis and decreases formation of myeloperoxidase, or MPO, TNF, MIP-1alpha, and IL-1 in the lungs of mice challenged with LPS; and (ii) increases the survival rate of mice in which sepsis was induced by a lethal injection of LPS. The siRNA is against Factor 5A are currently being tested in several preclinical *in-vivo* inflammatory disease models. Other experiments utilizing siRNA to Factor 5A include inhibition of cell death, or apoptosis, during the processing of mouse pancreatic beta islet cells for transplantation, and the inhibition of viral replication in a human cell line infected with HIV-1.

Proteins required for cell death include p53, interleukins and other cytokines, caspases, and TNF-a. Expression of these cell death proteins is required for the execution of apoptosis. We have found that downregulating Factor 5A by treatment with siRNA, inhibits the expression of p53, a major cell death transcription factor that in turn controls the formation of a suite of other cell death proteins. In addition, down-regulation of Factor 5A up-regulates Bcl-2, a major suppressor of apoptosis.

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Accelerating Apoptosis

In preclinical studies, we have also established that up-regulation of Factor 5A isoform induces death in cancer cells through both the p53 (intrinsic) and cell death receptor (extrinsic) apoptotic pathways. Tumors arise when cells that have been targeted by the immune system to undergo apoptosis are unable to do so because of an inability to activate the apoptotic pathways. Just as the senescence Factor 5A gene appears to facilitate expression of the entire suite of genes required for programmed cell death in plants, the apoptosis Factor 5A gene appears to regulate expression of a suite of genes required for programmed cell death in human cells. Because the Factor 5A gene appears to function at the initiation point of the apoptotic pathways, both intrinsic and extrinsic, we believe that our gene technology has potential application as a means of combating a broad range of cancers. We have found, in in-vitro studies, that up-regulating the apoptosis isoform of Factor 5A results in: the up-regulation of p53, an important tumor suppressor gene that promotes apoptosis in cells with damaged DNA; inflammatory cytokine production; increased cell death receptor formation; and caspase activity. These features, coupled with a simultaneous down-regulation Bcl-2, a suppressor of apoptosis, and telomerase, result in apoptosis of cancer cells. In addition, in-vitro studies have shown that up-regulation of Factor 5A also down-regulates VEGF, a growth factor which allows tumors to develop additional vascularization needed for growth beyond a small mass of cells.

Human Health Target Markets

We believe that our gene technology could have broad applicability in the human health field, by either inhibiting or accelerating apoptosis. Inhibiting apoptosis may be useful in preventing or treating a wide range of inflammatory and ischemic diseases attributed to premature apoptosis, including heart disease, arthritis, ocular diseases, such as glaucoma, and neurodegenerative diseases among others. Accelerating apoptosis may be useful in treating certain forms of cancer because the body s immune system is not able to force cancerous cells to undergo apoptosis.

Agricultural Applications

Our research focuses on the discovery and development of certain gene technologies, which are designed to confer positive traits on fruits, flowers, vegetables, forestry species and agronomic crops. To date, we have isolated and characterized the senescence-induced Lipase gene, DHS, and Factor 5A in certain species of plants. Our goal is to modulate the expression of these genes in order to achieve such traits as extended shelf life, increased biomass, increased yield and increased resistance to environmental stress and disease, thereby demonstrating proof of concept in each category of crop.

Certain agricultural results to date include:

- Longer shelf life of perishable produce;
- Increased biomass and seed yield;
- Greater tolerance to environmental stresses, such as drought and soil salinity;
- Greater tolerance to certain fungal and bacterial pathogens;
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- More efficient use of fertilizer; and
- Advancement of field trials in banana, lettuce, trees, and bedding plants.

The technology presently utilized by the industry for increasing the shelf life in certain flowers, fruits and vegetables relies primarily on reducing ethylene biosynthesis, and hence only has application to the limited number of crops that are ethylene-sensitive. Because Factor 5A, DHS and lipase are already present in all plant cells, our technology may be incorporated into crops by using either conventional breeding methods (non-genetically modified) or biotechnology gene suppression techniques.

We have licensed this technology to various strategic partners and have entered into a joint venture, and we intend to continue to license this technology to additional strategic partners and/or enter into additional joint ventures. Together with our commercial partners, we are currently working with lettuce, turfgrass, tomato, canola, *Arabidopsis* (a model plant that is similar to canola), banana, alfalfa, and certain species of trees and bedding plants, and we have obtained proof of concept for enhanced shelf life, seed yield, biomass, and resistance to disease in several of these plants. We have ongoing field trials of certain trees, lettuce and bananas with our respective partners. The first round of lettuce field trials showed that our technology reduced browning of cut lettuce. The first and second round of banana field trials have shown that our technology extends the shelf life of banana fruit by 100%. In addition to the shelf life benefits, field trials conducted during the winter of 2004-2005 generated encouraging disease tolerance data specific to Black Sigatoka (Black Leaf Streak Disease), for banana plants. Additional field trials for banana plants are planned for Black Sigatoka. Commercialization by our partners may require a combination of traits in a crop, such as both shelf life and disease resistance, or other traits. Our near-term research and development initiatives include modulating the expression of DHS and Factor 5A genes in these plants and then propagation and phenotype testing of such plants.

Our ongoing research and development initiatives for agriculture include:

• Further developing and implementing the DHS and Factor 5A gene technology in lettuce, banana, oil seed crops, turfgrass, bedding plants, tomato, alfalfa, corn, soybean and trees; and

• Testing the resultant crops for new beneficial traits such as increased yield, increased tolerance to environmental stress, disease resistance and more efficient use of fertilizer.

Agricultural Target Markets

In order to address the complexities associated with marketing and distribution in the worldwide market, we have adopted a multi-faceted commercialization strategy, in which we plan to enter into licensing agreements or other strategic relationships with a variety of companies or other entities on a crop-by-crop basis.

Because the agricultural market is dominated by privately held companies or subsidiaries of foreign owned companies, market size and market share data for the crops under our license

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and development agreements is not readily available. Additionally, because we have entered into confidentiality agreements with our license and development partners, we are unable to report the specific financial terms of the agreements as well as any market size and market share data that our partners may have disclosed to us regarding their companies.

Development and License Agreements

In November 2001, we entered into a worldwide exclusive development and license agreement with the Harris Moran Seed Company, referred to herein as the Harris Moran License, to commercialize our technology in lettuce and certain melons for an indefinite term, unless terminated by either party pursuant to the terms of the agreement. To date, the development steps performed by Harris Moran and us have all been completed in accordance with the protocol set forth in the Harris Moran License. There has been extensive characterization of our genes in lettuce in a laboratory setting. The initial lab work has produced genetically modified seed under greenhouse containment, which has been followed by substantial field trials for evaluation. These field trials represent a vital step in the process necessary to develop a commercial product. Additional laboratory and field experiments and development are necessary for development of cut, bagged lettuce. Harris Moran is in the process of performing additional field trials of our technology. Ongoing field trial results will determine if non-genetically modified seed will produce sufficiently reduced browning traits to attract potential marketing partners. Additional field work in lettuce is targeting traits other than browning, such as disease resistance and yield. Under the Harris Moran License, we have received an upfront payment and we may receive benchmark payments upon achievement of certain research and marketing milestones.

In June 2002, we entered into a three-year worldwide exclusive development and option agreement with ArborGen, LLC, referred to herein as the ArborGen Agreement, to develop our technology in certain species of trees. The ArborGen Agreement also granted ArborGen an option to acquire an exclusive worldwide license to commercialize our technology in various other forestry products. In June 2006, ArborGen exercised their option to license our technology. To date, the research being conducted by ArborGen has proceeded according to schedule. ArborGen has seen promising positive growth responses in greenhouse-grown seedlings. These initial greenhouse data led to the initiation of field trials by ArborGen in the second half of calendar 2004. At the end of the 2005 growing season, certain trees which were enhanced by our technology had approximately double the increase in volume relative to control trees. Under the ArborGen Agreement, we have received an upfront payment and benchmark payments, and upon finalization of a license agreement, we may receive additional benchmark payments upon achievement of certain development milestones and royalties upon commercialization.

In September 2002, we entered into an exclusive development and license agreement with Cal/West Seeds, referred to herein as the Cal/West License, to commercialize our technology in certain varieties of alfalfa. The Cal/West License will continue until the expiration of the patents set forth in the agreement, unless terminated earlier by either party pursuant to the terms of the agreement. The Cal/West License also grants Cal/West an exclusive option to develop our technology in various other forage crops. The Cal/West development effort successfully incorporated our technology into their alfalfa seed as of July 2004.

Greenhouse trait analysis is ongoing. Under the Cal/West License, we have received an upfront payment and we may receive benchmark payments as certain development milestones are achieved and a royalty upon commercialization based upon the volume of alfalfa seed sold that contains our technology.

In March 2004, we entered into an exclusive development and license agreement with The Scotts Company, referred to herein as the Scotts Agreement, to commercialize our technology in turfgrass and certain species of bedding plants. Scotts is working on incorporating our technology to enhance a variety of traits in these plants, including environmental stress resistance, disease resistance and enhanced bloom properties. We are collaborating with Scotts in the areas of ornamental bedding plants and turfgrass. A large-scale greenhouse evaluation of bedding plants is being conducted. Preliminary results have given insight into how to proceed with additional development. Transformation and initial tissue culture screening of events have been undertaken in turfgrass. In tissue culture, turfgrass containing our technology has grown more successfully than control turfgrass without our technology. Greenhouse testing of the grass containing our technology is the next planned development and license agreement with The Scotts Company was amended. Due to a change in the corporate financial policy at Scotts, Scotts requested to defer certain milestone payments, which were to be made on a calendar basis. We agreed and these payments have now been deferred and incorporated in the amount to be paid to us upon commercialization. Additionally, the commercialization fee has been increased. All other aspects of the agreement remain unchanged, and the project continues to move forward without interruption. We may also receive royalties upon commercialization from the net sales of turfgrass seed and bedding plants containing our technology .

In October 2005, we entered into a license agreement with the Broin Companies to license our proprietary gene technology to Broin to improve aspects of Broin s ethanol production capabilities. We are currently working on incorporating our technology into those aspects of Broin s ethanol production. We will receive an annual payment for each Broin facility that incorporates our technology. If Broin incorporates our technology into each of its facilities, we would receive an annual payment in excess of \$1,000,000.

Joint Venture

On May 14, 1999, we entered into a joint venture agreement with Rahan Meristem Ltd., or Rahan Meristem, an Israeli company engaged in the worldwide export marketing of banana germplasm, referred to herein as the Rahan Joint Venture. In general, bananas are grown either for local domestic consumption or grown for export. According to the Food and Agriculture Organization of the United Nations, there were 12 million metric tons of bananas exported in 2002. The level of production equates to the fruit of approximately 480 million banana plants. A percentage of these plants are replaced each year with new banana seedlings. Rahan Meristem accounts for approximately 10% of the worldwide export of enhanced banana seedlings.

We have contributed, by way of a limited, exclusive, worldwide license to the Rahan Joint Venture, access to our technology, discoveries, inventions and know-how, whether patentable or otherwise, pertaining to plant genes and their cognate expressed proteins that are

induced during senescence for the purpose of developing, on a joint basis, genetically enhanced banana plants which will result in a banana that has a longer shelf life. Rahan Meristem has contributed its technology, inventions and know-how with respect to banana plants. Rahan Meristem and Senesco equally own the Rahan Joint Venture and have equally shared the expense of field trials.

The Rahan Joint Venture applied for and received a conditional grant that totals approximately \$340,000, which constituted 50% of the Rahan Joint Venture s research and development budget over the five-year period, ending on May 31, 2005, from the Israel - U.S. Binational Research and Development Foundation, or BIRD Foundation, referred to herein as the BIRD Grant. Such grant, along with certain royalty payments, shall only be repaid to the BIRD Foundation upon the commercial success of the Rahan Joint Venture s technology. The commercial success is measured based upon certain benchmarks and/or milestones achieved by the Rahan Joint Venture. The Rahan Joint Venture reports these benchmarks periodically to the BIRD Foundation.

All aspects of the Rahan Joint Venture s research and development initiative are proceeding on time, or are ahead of the original schedule laid out at the inception of the Rahan Joint Venture. Both the DHS and lipase genes have been identified and isolated in banana, and the Rahan Joint Venture is currently in the process of silencing these genes. Two Israeli field trials indicated that Senesco s proprietary technology extends the shelf life of the banana fruit up to 100%, while allowing the banana fruit to ripen normally. Later field trials have shown promising disease tolerance results and we are currently performing additional field trials to further assess disease tolerance. We believe that these field trials have yielded data sufficient to initiate contact with potential marketing partners. However, as the banana modified with our technology may be considered a GMO, shelf life extension may have to be combined with disease tolerance to gain acceptance by the growers.

Competition

Our competitors in both human health and agriculture that are presently attempting to distribute their technology have generally utilized one of the following distribution channels:

- licensing technology to major marketing and distribution partners;
- entering into strategic alliances; or
- developing in-house production and marketing capabilities.

In addition, some competitors are owned by established distribution companies, which alleviates the need for strategic alliances, while others are attempting to create their own distribution and marketing channels.

Our competitors in the field of delaying plant senescence are companies that develop and produce transformed plants with a variety of enhanced traits. Such companies include: Icora (formerly Paradigm Genetics); Bayer Crop Science; Mendel Biotechnology; Renessen LLC; Exelixis Plant Sciences, Inc.; Syngenta International AG; and Eden Bioscience, among others.

There are many large and development stage companies working in the field of apoptosis

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research including: Amgen; Centocor; Genzyme; OSI Pharmaceuticals, Inc.; Idun Pharmaceuticals; Novartis; Introgen Therapeutics, Inc.; Genta, Inc.; and Vertex Pharmaceuticals, Inc., among others.

Marketing Program

We presently license our technology to agricultural companies capable of incorporating our technology into crops grown for commercial agriculture. We anticipate revenues from these relationships in the form of licensing fees and royalties from our partners, usage fees in the case of the agreement with the Broin Company, or sharing gross profits in the case of the joint venture with Rahan Meristem. In addition, we anticipate payments from our partners upon our achievement of certain research and development benchmarks. This commercialization strategy allows us to generate revenues at various stages of product development, while ensuring that our technology is incorporated into a wide variety of crops. Our optimal partners combine the technological expertise to incorporate our technology into their product line along with the ability to successfully market the enhanced final product, thereby eliminating the need for us to develop and maintain a sales force. Through June 30, 2006, we have entered into five license and development agreements and one joint venture with established agricultural biotechnology companies.

Generally, projects with our license and joint venture partners begin by transforming seed or germplasm to incorporate our technology. Those seeds or germplasm are then grown in our partners greenhouse. After successful greenhouse trials, our partners will transfer the plants to the field for field trials. After completion of successful field trials, our partners may have to apply for and receive regulatory approval prior to initiation of any commercialization activities.

Generally, the approximate time to complete each development step is as follows:

Seed Transformation	approximately 1 to 2 years
Greenhouse	approximately 1 to 2 years
Field Trials	approximately 2 to 5 years

The actual amount of time spent on each development phase depends on the crop, its growth cycle and the success of the transformation achieving the desired results. As such, the amount of time for each phase of development could vary, or the time frames may change.

The development of our technology with The Broin Company is different than our other licenses in that we are modifying certain production inputs for ethanol. That process involves modifying the inputs, testing such inputs in Broin s production process and if successful, implementing such inputs in Broin s production process on a plant by plant basis.

The status of each of our projects with our partners is as follows:

Project	Partner	Status
Banana	Rahan Meristem	
-Shelf Life		Field Trials
-Disease Resistance		Field Trials
Lettuce	Harris Moran	
-Browning		Field Trials
-Disease Resistance		Field Trials
Trees	Arborgen	
-Growth		Field Trials
Alfalfa	Cal/West	Greenhouse
Turfgrass	The Scotts Company	Seed Transformation
Bedding Plants	The Scotts Company	Greenhouse
Ethanol	The Broin Company	Modify Inputs

Commercialization by our partners may require a combination of traits in a crop, such as both shelf life and disease resistance, or other traits.

Based upon our commercialization strategy, we anticipate that there may be a significant period of time before plants enhanced using our technology reach consumers. Thus, we have not begun to actively market our technology directly to consumers, but rather, we have sought to establish ourselves within the industry through presentations at industry conferences, our website and direct communication with prospective licensees.

Consistent with our commercialization strategy, we intend to attract other companies interested in strategic partnerships, joint ventures or licensing our technology. The Harris Moran License, the ArborGen Agreement, the Cal/West License, the Broin Agreement and the Rahan Joint Venture are the first successes toward the execution of our strategy.

We plan to employ the same partnering strategy in both the human health and agricultural target markets. Our preclinical research has yielded data that we have presented to various biopharmaceutical companies that may be prospective licensees for the development and marketing of potential applications of our technology. Consistent with our commercialization strategy, we intend to attract other companies interested in strategic partnerships or licensing our technology, which may result in additional license fees, revenues from contract research and other related revenues. Additionally, we may select some human health indications to bring into clinical trials on our own. Successful future operations will depend on our ability to transform our research and development activities into a commercially feasible technology.

Research Program

Our research and development is performed by third party researchers at our direction, pursuant to various research and license agreements. The primary research and development effort, which is performed by approximately 22 researchers that are funded in whole or in part by us, takes place at the University of Waterloo in Ontario, Canada, where the technology was discovered, Mayo Clinic, the University of Virginia, and the University of Colorado. Additional research and development is performed by our partners in connection with the Harris Moran License, the Scotts Agreement, the ArborGen Agreement, the Cal/West License, the Broin License, and through the Rahan Joint Venture.