

SOLIGENIX, INC.
Form SC 13D/A
January 02, 2013

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

SCHEDULE 13D/A3 (Amendment No. 3)

Under the Securities Exchange Act of 1934

Soligenix, Inc.
(Name of Issuer)

Common Stock, Par Value \$0.001 per share
(Title of Class of Securities)

258094101
(CUSIP Number)

James Robinson, Esq.
Cahill Gordon & Reindel llp
80 Pine Street
New York, NY 10005
(212) 701-3000

(Name, Address and Telephone Number of Person Authorized to Receive Notices and Communications)

December 20, 2012
(Date of Event which Requires Filing of this Statement)

If the filing person has previously filed a statement on Schedule 13G to report the acquisition that is the subject of this Schedule 13D, and is filing this schedule because of §§ 240.13d-1(e), 240.13d-1(f) or 240.13d-1(g), check the following box [X].

NOTE: Schedules filed in paper format shall include a signed original and five copies of the schedule, including all exhibits. See Rule 240.13d-7 for other parties to whom copies are to be sent.

*The remainder of this cover page shall be filled out for a reporting person's initial filing on this form with respect to the subject class of securities, and for any subsequent amendment containing information which would alter disclosures provided in a prior cover page.

The information required on the remainder of this cover page shall not be deemed to be "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934 ("Act") or otherwise subject to the liabilities of that section of the Act but shall be subject to all other provisions of the Act (however, see the Notes).

CUSIP No. 258094101

- (1) NAME OF REPORTING PERSONS
I.R.S. IDENTIFICATION NOS. OF ABOVE PERSONS (entities only)
Paolo Cavazza
- (2) CHECK THE APPROPRIATE BOX IF A MEMBER OF A GROUP (See Instructions)
(a)
(b)
- (3) SEC USE ONLY
- (4) SOURCE OF FUNDS
AF, PF
- (5) CHECK IF DISCLOSURE OF LEGAL PROCEEDINGS IS REQUIRED PURSUANT TO
ITEMS 2(d) or 2(e)
- (6) CITIZENSHIP OR PLACE OF ORGANIZATION
Italy
- | | | |
|--------------|------|--------------------------|
| Number of | (7) | SOLE VOTING POWER |
| Shares | | 59,539 |
| Beneficially | (8) | SHARED VOTING POWER |
| Owned | | 3,320,411 |
| by Each | (9) | SOLE DISPOSITIVE POWER |
| Reporting | | 59,539 |
| Person | (10) | SHARED DISPOSITIVE POWER |
| With | | 3,320,411 |
- (11) AGGREGATE AMOUNT BENEFICIALLY OWNED BY EACH REPORTING PERSON
3,379,950
- (12) CHECK IF THE AGGREGATE AMOUNT IN ROW (11) EXCLUDES CERTAIN SHARES
- (13) PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (11)
29.1% (based on 11,160,573 shares of Common Stock outstanding as of November 7, 2012, as reported in the Issuer's Quarterly Report on Form 10-Q, filed pursuant to the Securities Exchange Act of 1934, as amended, with the Securities and Exchange Commission on November 14, 2012, plus 444,873 shares of Common Stock issuable upon exercise of the 2012 Warrants (as defined below)).
- (14) TYPE OF REPORTING PERSON
IN

CUSIP No. 258094101

- (1) NAME OF REPORTING PERSONS
I.R.S. IDENTIFICATION NOS. OF ABOVE PERSONS (entities only)
Sigma-Tau Finanziaria S.p.A.
- (2) CHECK THE APPROPRIATE BOX IF A MEMBER OF A GROUP (See Instructions)
(a)
(b)
- (3) SEC USE ONLY
- (4) SOURCE OF FUNDS
AF
- (5) CHECK IF DISCLOSURE OF LEGAL PROCEEDINGS IS REQUIRED PURSUANT TO
ITEMS 2(d) or 2(e)
- (6) CITIZENSHIP OR PLACE OF ORGANIZATION
Italy
- | | | |
|--------------|------|--------------------------|
| Number of | (7) | SOLE VOTING POWER |
| Shares | | 0 |
| Beneficially | (8) | SHARED VOTING POWER |
| Owned | | 3,068,461 |
| by Each | (9) | SOLE DISPOSITIVE POWER |
| Reporting | | 0 |
| Person | (10) | SHARED DISPOSITIVE POWER |
| With | | 3,068,461 |
- (11) AGGREGATE AMOUNT BENEFICIALLY OWNED BY EACH REPORTING PERSON
3,068,461
- (12) CHECK IF THE AGGREGATE AMOUNT IN ROW (11) EXCLUDES CERTAIN SHARES
- (13) PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (11)
26.6% (based on 11,160,573 shares of Common Stock outstanding as of November 7, 2012, as reported in the Issuer's Quarterly Report on Form 10-Q, filed pursuant to the Securities Exchange Act of 1934, as amended, with the Securities and Exchange Commission on November 14, 2012, plus 357,069 shares of Common Stock issuable upon exercise of the Pharmaceuticals 2012 Warrant (as defined below)).
- (14) TYPE OF REPORTING PERSON
CO

CUSIP No. 258094101

- (1) NAME OF REPORTING PERSONS
I.R.S. IDENTIFICATION NOS. OF ABOVE PERSONS (entities only)
Sigma-Tau International S.A.
- (2) CHECK THE APPROPRIATE BOX IF A MEMBER OF A GROUP (See Instructions)
(a)
(b)
- (3) SEC USE ONLY
- (4) SOURCE OF FUNDS
AF
- (5) CHECK IF DISCLOSURE OF LEGAL PROCEEDINGS IS REQUIRED PURSUANT TO
ITEMS 2(d) or 2(e)
- (6) CITIZENSHIP OR PLACE OF ORGANIZATION
Luxembourg
- | | | |
|--------------|------|--------------------------|
| Number of | (7) | SOLE VOTING POWER |
| Shares | | 0 |
| Beneficially | (8) | SHARED VOTING POWER |
| Owned | | 3,068,461 |
| by Each | (9) | SOLE DISPOSITIVE POWER |
| Reporting | | 0 |
| Person | (10) | SHARED DISPOSITIVE POWER |
| With | | 3,068,461 |
- (11) AGGREGATE AMOUNT BENEFICIALLY OWNED BY EACH REPORTING PERSON
3,068,461
- (12) CHECK IF THE AGGREGATE AMOUNT IN ROW (11) EXCLUDES CERTAIN SHARES
- (13) PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (11)
26.6% (based on 11,160,573 shares of Common Stock outstanding as of November 7, 2012, as reported in the Issuer's Quarterly Report on Form 10-Q, filed pursuant to the Securities Exchange Act of 1934, as amended, with the Securities and Exchange Commission on November 14, 2012, plus 357,069 shares of Common Stock issuable upon exercise of the Pharmaceuticals 2012 Warrant (as defined below)).
- (14) TYPE OF REPORTING PERSON
CO

CUSIP No. 258094101

- (1) NAME OF REPORTING PERSONS
I.R.S. IDENTIFICATION NOS. OF ABOVE PERSONS (entities only)
Sigma-Tau America S.A.
- (2) CHECK THE APPROPRIATE BOX IF A MEMBER OF A GROUP (See Instructions)
(a)
(b)
- (3) SEC USE ONLY
- (4) SOURCE OF FUNDS
AF
- (5) CHECK IF DISCLOSURE OF LEGAL PROCEEDINGS IS REQUIRED PURSUANT TO
ITEMS 2(d) or 2(e)
- (6) CITIZENSHIP OR PLACE OF ORGANIZATION
Luxembourg
- | | | |
|--------------|------|--------------------------|
| Number of | (7) | SOLE VOTING POWER |
| Shares | | 0 |
| Beneficially | (8) | SHARED VOTING POWER |
| Owned | | 3,068,461 |
| by Each | (9) | SOLE DISPOSITIVE POWER |
| Reporting | | 0 |
| Person | (10) | SHARED DISPOSITIVE POWER |
| With | | 3,068,461 |
- (11) AGGREGATE AMOUNT BENEFICIALLY OWNED BY EACH REPORTING PERSON
3,068,461
- (12) CHECK IF THE AGGREGATE AMOUNT IN ROW (11) EXCLUDES CERTAIN SHARES
- (13) PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (11)
26.6% (based on 11,160,573 shares of Common Stock outstanding as of November 7, 2012, as reported in the Issuer's Quarterly Report on Form 10-Q, filed pursuant to the Securities Exchange Act of 1934, as amended, with the Securities and Exchange Commission on November 14, 2012, plus 357,069 shares of Common Stock issuable upon exercise of the Pharmaceuticals 2012 Warrant (as defined below)).
- (14) TYPE OF REPORTING PERSON
CO

CUSIP No. 258094101

- (1) NAME OF REPORTING PERSONS
I.R.S. IDENTIFICATION NOS. OF ABOVE PERSONS (entities only)
Sigma-Tau Pharmaceuticals, Inc.
- (2) CHECK THE APPROPRIATE BOX IF A MEMBER OF A GROUP (See Instructions)
(a)
(b)
- (3) SEC USE ONLY
- (4) SOURCE OF FUNDS
WC
- (5) CHECK IF DISCLOSURE OF LEGAL PROCEEDINGS IS REQUIRED PURSUANT TO
ITEMS 2(d) or 2(e)
- (6) CITIZENSHIP OR PLACE OF ORGANIZATION
Nevada
- | | | |
|--------------|------|--------------------------|
| Number of | (7) | SOLE VOTING POWER |
| Shares | | 0 |
| Beneficially | (8) | SHARED VOTING POWER |
| Owned | | 3,068,461 |
| by Each | (9) | SOLE DISPOSITIVE POWER |
| Reporting | | 0 |
| Person | (10) | SHARED DISPOSITIVE POWER |
| With | | 3,068,461 |
- (11) AGGREGATE AMOUNT BENEFICIALLY OWNED BY EACH REPORTING PERSON
3,068,461
- (12) CHECK IF THE AGGREGATE AMOUNT IN ROW (11) EXCLUDES CERTAIN SHARES
- (13) PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (11)
26.6% (based on 11,160,573 shares of Common Stock outstanding as of November 7, 2012, as reported in the Issuer's Quarterly Report on Form 10-Q, filed pursuant to the Securities Exchange Act of 1934, as amended, with the Securities and Exchange Commission on November 14, 2012, plus 357,069 shares of Common Stock issuable upon exercise of the Pharmaceuticals 2012 Warrant (as defined below)).
- (14) TYPE OF REPORTING PERSON
CO

Item 1. Security and Issuer.

Item 1 of the Schedule 13D is hereby amended and restated in its entirety as follows:

This Amendment No. 3 by Paolo Cavazza, an Italian citizen, Sigma-Tau Finanziaria S.p.A., an Italian corporation (“Sigma-Tau Finanziaria”), Sigma-Tau International S.A., a Luxembourg corporation (“Sigma-Tau International”), Sigma-Tau America S.A., a Luxembourg corporation (“Sigma-Tau America”) and Sigma-Tau Pharmaceuticals, a Nevada Corporation (“Sigma-Tau Pharmaceuticals” and, together with Paolo Cavazza, Sigma-Tau Finanziaria, Sigma-Tau International and Sigma-Tau America, the “Reporting Parties”) amends the Schedule 13D filed with the SEC on February 20, 2009 as amended by Amendment No. 1 filed with the SEC on October 2, 2009 and Amendment No. 2 filed with the SEC on June 28, 2010 (the “Schedule 13D”) with respect to the Common Stock, \$0.001 par value (the “Common Stock”), of Soligenix, Inc. (formerly DOR BioPharma, Inc.) (the “Issuer”), a Delaware corporation whose principal offices are located at 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540. Since the filing of Amendment No. 2 to the Schedule 13D, Claudio Cavazza has ceased to be a beneficial owner of Common Stock as a result of his passing on June 6, 2011. On February 1, 2012, the Issuer completed a reverse stock split of its issued and outstanding shares of common stock at a ratio of 1-for-20, whereby every 20 shares of its common stock was exchanged for one share of its common stock (the “Reverse Stock Split”). All share numbers included in this Schedule 13D for the period commencing with February 1, 2012 give effect to the Reverse Stock Split.

Item 2. Identity and Background.

Item 2 of the Schedule 13D is hereby amended and restated in its entirety as follows:

This Schedule 13D is being filed jointly on behalf of Paolo Cavazza, Sigma-Tau Finanziaria, Sigma-Tau International, Sigma-Tau America and Sigma-Tau Pharmaceuticals. Paolo Cavazza directly and indirectly owns 38% of Sigma-Tau Finanziaria. Sigma-Tau International is a direct wholly-owned subsidiary of Sigma-Tau Finanziaria. Sigma-Tau America is a direct wholly-owned subsidiary of Sigma-Tau International. Sigma-Tau Pharmaceuticals is a direct wholly-owned subsidiary of Sigma-Tau America.

The business address of Sigma-Tau Finanziaria is Via Sudafrica, 20, Rome, Italy 00144. The principal business of Sigma Tau Finanziaria is as a parent holding company whose principal assets consist of the common stock of its subsidiaries which form a fully integrated pharmaceutical company operating in Europe, the United States and Africa.

The business address of Sigma-Tau International is 19-21 Boulevard du Prince Henri,

L-1724 Luxembourg. Sigma-Tau International is a subsidiary holding company whose principal assets consist of the common stock of its subsidiaries which form a fully integrated pharmaceutical company operating in Europe (excluding Italy), the United States and Africa.

The business address of Sigma-Tau America is 19-21 Boulevard du Prince Henri, L-1724 Luxembourg. Sigma-Tau America is a subsidiary holding company whose principal assets consist of the common stock of its subsidiaries which form a fully integrated pharmaceutical company operating mainly in the United States.

The business address of Sigma-Tau Pharmaceuticals is 9841 Washingtonian Boulevard, Suite 500, Gaithersburg, Maryland 20878. Sigma-Tau Pharmaceuticals is a pharmaceuticals company

engaged in the global development and commercialization of pharmaceuticals for patients with rare diseases.

The name, address, principal occupation or employment and citizenship of each of the executive officers and directors of, and each person, including Paolo Cavazza, controlling Sigma-Tau Finanziaria, Sigma-Tau International, Sigma-Tau America and Sigma-Tau Pharmaceuticals are set forth in Schedule A hereto. Neither the Reporting Parties nor any of the persons listed on Schedule A has been, during the last five years, (a) convicted in a criminal proceeding (excluding traffic violations or similar misdemeanors) or (b) a party to a civil proceeding of a judicial or administrative body of competent jurisdiction and as a result of such proceeding was or is subject to a judgment, decree or final order enjoining future violations of, or prohibiting or mandating activities subject to, federal or state securities laws or finding any violation with respect to such laws.

Item 3. Source and Amount of Funds or Other Consideration.

Item 3 of the Schedule 13D is hereby amended and restated in its entirety as follows:

In July 2006, Chaumiere-Consultadoria e Servicos SDC Unipessoal LDA (“Chaumire”) purchased 356,100 shares of Common Stock in the open market at an average cash purchase price of \$0.267 per share. Chaumiere used its working capital to purchase such shares. Chaumiere was an indirect wholly-owned subsidiary of Aptafin S.A. (“Aptafin”). Aptafin is owned by Paolo Cavazza and members of his family.

During the period from July 18, 2006 through September 8, 2006, Paolo Cavazza purchased 1,190,770 shares of Common Stock in the open market at an average cash purchase price of \$0.2713 per share. Paolo Cavazza used personal funds to purchase such shares.

On November 26, 2008, pursuant to a Letter of Intent, dated November 26, 2008, between the Issuer and Sigma-Tau Pharmaceuticals (the “Letter of Intent”), Sigma-Tau Pharmaceuticals purchased 16,666,667 shares of Common Stock at a cash purchase price of \$0.09 per share. Sigma-Tau Pharmaceuticals used its working capital to purchase such shares.

On February 11, 2009, pursuant to a Common Stock Purchase Agreement, dated as of February 11, 2009, between the Issuer and Sigma-Tau Pharmaceuticals (the “February 2009 Purchase Agreement”), Sigma-Tau Pharmaceuticals purchased 25,000,000 shares of Common Stock at a cash purchase price of \$0.18 per share. Sigma-Tau Pharmaceuticals used its working capital to purchase such shares.

On September 24, 2009, pursuant to a Securities Purchase Agreement, dated as of September 23, 2009, among the Issuer, Sigma-Tau Pharmaceuticals and the other Investors identified therein (the “September 2009 Purchase Agreement”), Sigma-Tau Pharmaceuticals agreed to purchase and, on September 28, 2009, Sigma-Tau Pharmaceuticals purchased, 3,952,569 shares of Common Stock at a cash purchase price of \$0.253 per share. Sigma-Tau Pharmaceuticals used its working capital to purchase such shares. In consideration of the purchase of such shares, the Issuer issued a warrant to Sigma-Tau Pharmaceuticals to purchase 1,976,284 shares of Common Stock (the “2009 Warrant”), that was exercisable at a price of \$0.278 per share, in whole or in part, at any time and from time to time from September 28, 2009 through September 27, 2014. The expiration date of the Warrant could be accelerated at the Issuer’s option if the shares of Common Stock met certain price thresholds and the Common Stock underlying the 2009 Warrant was registered for resale pursuant to an effective registration statement or was freely transferable without volume restrictions pursuant to Rule 144 under the Securities Act of 1933, as amended (the “Securities Act”).

In May 2010, Chaumiere changed its name to Chaumiere Sarl.

On June 18, 2010, pursuant to a Securities Purchase Agreement, dated as of June 15, 2010 among the Issuer, Sigma-Tau Pharmaceuticals, Chaumiere Sarl and the other Investors identified therein (the “June 2010 Purchase Agreement”), Sigma-Tau Pharmaceuticals and Chaumiere Sarl agreed to purchase and, on June 18, 2010, Sigma-Tau Pharmaceuticals and Chaumiere Sarl purchased, 8,608,580 shares and 2,926,829 shares, respectively, of Common Stock at a cash purchase price of \$0.205 per share. Sigma-Tau Pharmaceuticals and Chaumiere Sarl each used its working capital to purchase such shares. In consideration of the purchase of such shares, the Issuer issued a warrant to Sigma-Tau Pharmaceuticals to purchase 5,165,148 shares of Common Stock (the “Pharmaceuticals 2010 Warrant”) and a warrant to Chaumiere Sarl to purchase 1,756,097 shares of Common Stock (the “Chaumiere 2010 Warrant” and, together with the Pharmaceuticals 2010 Warrant, the “2010 Warrants”), in each case that was exercisable at a price of \$0.28 per share, in whole or in part, at any time and from time to time from June 18, 2010 through June 18, 2015. The expiration date of the 2010 Warrants could be accelerated at the Issuer’s option if the shares of Common Stock met certain price thresholds and the Common Stock underlying the 2010 Warrants was registered for resale pursuant to an effective registration statement or was freely transferable without volume restrictions pursuant to Rule 144 under the Securities Act.

On June 29, 2010, Chaumiere merged with and into Sinaf S.A. (“Sinaf”), its direct parent and a direct wholly-owned subsidiary of Aptafin, and Sinaf thereby became the direct beneficial owner of the shares of Common Stock beneficially owned by Chaumiere immediately prior to the merger.

On December 20, 2012, in conjunction with the execution of an amendment to a collaboration and supply agreement among the Issuer, a wholly-owned subsidiary of the Issuer and Sigma-Tau Pharmaceuticals, the Issuer issued a new warrant to purchase 357,069 shares of Common Stock to Sigma-Tau Pharmaceuticals (the “Pharmaceuticals 2012 Warrant”) in exchange for the 2009 Warrant and the Pharmaceuticals 2010 Warrant and issued a new warrant to purchase 87,804 shares of Common Stock to Sinaf (the “Sinaf 2012 Warrant” and, together with the Pharmaceuticals 2012 Warrant, the “2012 Warrants”) in exchange for the Chaumiere 2010 Warrant. The 2012 Warrants are exercisable at a price of \$0.53 per share, in whole or in part, at any time and from time to time from June 19, 2013 through December 19, 2017. The expiration date of the 2012 Warrants may be accelerated at the Issuer’s option if the shares of Common Stock meet certain price thresholds and the Common Stock underlying the 2012 Warrant is registered for resale pursuant to an effective registration statement or is freely transferable without volume limitations pursuant to Rule 144 under the Securities Act.

Item 4. Purpose of the Transaction.

Item 4 of the Schedule 13D is hereby amended and restated in its entirety as follows:

The purpose of the transactions was to acquire equity investment interests in the Issuer and to support the Issuer in its development of Beclomethasone Dipropionate.

The February 2009 Purchase Agreement provides that, to the extent Sigma-Tau Pharmaceuticals continues to beneficially own ten percent of the Common Stock issued by the Issuer, Sigma-Tau Pharmaceuticals shall have the right to nominate one member of the Issuer’s Board of Directors, who shall be reasonably satisfactory to the Issuer.

The Issuer undertook in the February 2009 Purchase Agreement to use the proceeds from the sale of the stock pursuant to the Letter of Intent and the February 2009 Purchase Agreement only for the furtherance of a phase 3 clinical study relating to Beclomethasone Dipropionate and product development activities necessary to obtain and maintain the authorizations from regulatory authorities necessary

for the marketing, use, distribution and sale of such product. The September 2009 Purchase Agreement and the June 2010 Purchase Agreement each provides that the net proceeds from the offer and sale of the securities thereunder will be used to advance the preclinical, clinical and regulatory development of the Issuer's drug and vaccine candidates. A portion of the net proceeds shall also be used for general corporate purposes, including the maintenance of in-licensed patent rights and proprietary intellectual property patent applications and patents. No portion of the net proceeds will be used to redeem outstanding securities of the Issuer.

Other than as set forth above, none of the Reporting Parties has any present plans or proposals which relate to or would result in any transaction, change or event specified in clauses (a) through (j) of Item 4 of Schedule 13D.

Item 5. Interest in Securities of Issuer.

Item 5 of the Schedule 13D is hereby amended and restated in its entirety as follows:

(a) Paolo Cavazza is the beneficial owner of 3,379,950 shares of Common Stock representing 29.1% (based on 11,160,573 shares of Common Stock outstanding as of November 7, 2012, as reported in the Issuer's Quarterly Report on Form 10-Q, filed pursuant to the Securities Exchange Act of 1934, as amended, with the Securities and Exchange Commission on November 14, 2012, plus 444,873 shares of Common Stock issuable upon exercise of the 2012 Warrants).

Sigma-Tau Finanziaria is the beneficial owner of 3,068,461 shares of Common Stock representing 26.6% (based on 11,160,573 shares of Common Stock outstanding as of November 7, 2012, as reported in the Issuer's Quarterly Report on Form 10-Q, filed pursuant to the Securities Exchange Act of 1934, as amended, with the Securities and Exchange Commission on November 14, 2012, plus 357,069 shares of Common Stock issuable upon exercise of the Pharmaceuticals 2012 Warrant).

Sigma-Tau International is the beneficial owner of 3,068,461 shares of Common Stock representing 26.6% (based on 11,160,573 shares of Common Stock outstanding as of November 7, 2012, as reported in the Issuer's Quarterly Report on Form 10-Q, filed pursuant to the Securities Exchange Act of 1934, as amended, with the Securities and Exchange Commission on November 14, 2012, plus 357,069 shares of Common Stock issuable upon exercise of the Pharmaceuticals 2012 Warrant).

Sigma-Tau America is the beneficial owner of 3,068,461 shares of Common Stock representing 26.6% (based on 11,160,573 shares of Common Stock outstanding as of November 7, 2012, as reported in the Issuer's Quarterly Report on Form 10-Q, filed pursuant to the Securities Exchange Act of 1934, as amended, with the Securities and Exchange Commission on November 14, 2012, plus 357,069 shares of Common Stock issuable upon exercise of the Pharmaceuticals 2012 Warrant).

Sigma-Tau Pharmaceuticals is the beneficial owner of 3,068,461 shares of Common Stock representing 26.6% (based on 11,160,573 shares of Common Stock outstanding as of November 7, 2012, as reported in the Issuer's Quarterly Report on Form 10-Q, filed pursuant to the Securities Exchange Act of 1934, as amended, with the Securities and Exchange Commission on November 14, 2012, plus 357,069 shares of Common Stock issuable upon exercise of the Pharmaceuticals 2012 Warrant).

(b) The number of shares of Common Stock as to which Paolo Cavazza has the sole power to vote or direct the vote is 59,539. The number of shares of Common Stock as to which Paolo Cavazza shares the power to vote or direct the vote is 3,320,411. The number of shares of Common Stock as to which Paolo Cavazza has the sole power to dispose or direct the disposition is 59,539. The

number of shares of Common Stock as to which Paolo Cavazza shares the power to dispose or direct the disposition is 3,320,411.

The number of shares of Common Stock as to which Sigma-Tau Finanziaria has the sole power to vote or direct the vote is zero. The number of shares of Common Stock as to which Sigma-Tau Finanziaria shares the power to vote or direct the vote is 3,068,461. The number of shares of Common Stock as to which Sigma-Tau Finanziaria has the sole power to dispose or direct the disposition is zero. The number of shares of Common Stock as to which Sigma-Tau Finanziaria shares the power to dispose or direct the disposition is 3,068,461.

The number of shares of Common Stock as to which Sigma-Tau International has the sole power to vote or direct the vote is zero. The number of shares of Common Stock as to which Sigma-Tau International shares the power to vote or direct the vote is 3,068,461. The number of shares of Common Stock as to which Sigma-Tau International has the sole power to dispose or direct the disposition is zero. The number of shares of Common Stock as to which Sigma-Tau International shares the power to dispose or direct the disposition is 3,068,461.

The number of shares of Common Stock as to which Sigma-Tau America has the sole power to vote or direct the vote is zero. The number of shares of Common Stock as to which Sigma-Tau America shares the power to vote or direct the vote is 3,068,461. The number of shares of Common Stock as to which Sigma-Tau America has the sole power to dispose or direct the disposition is zero. The number of shares of Common Stock as to which Sigma Tau America shares the power to dispose or direct the disposition is 3,068,461.

The number of shares of Common Stock as to which Sigma-Tau Pharmaceuticals has the sole power to vote or direct the vote is zero. The number of shares of Common Stock as to which Sigma-Tau Pharmaceuticals shares the power to vote or direct the vote is 3,068,461. The number of shares of Common Stock as to which Sigma-Tau Pharmaceuticals has the sole power to dispose or direct the disposition is zero. The number of shares of Common Stock as to which Sigma-Tau Pharmaceuticals shares the power to dispose or direct the disposition is 3,068,461.

(c) On December 20, 2012, in conjunction with the execution of an amendment to a collaboration and supply agreement among the Issuer, a wholly-owned subsidiary of the Issuer, and Sigma-Tau Pharmaceuticals, the Issuer issued a new warrant to purchase 357,069 shares of Common Stock to Sigma-Tau Pharmaceuticals (the “Pharmaceuticals 2012 Warrant”) in exchange for the 2009 Warrant and the Pharmaceuticals 2010 Warrant and issued a new warrant to purchase 87,804 shares of Common Stock to Sinaf (together with the Pharmaceuticals 2012 Warrant, the “2012 Warrants”) in exchange for the Chaumiere 2010 Warrant. The 2012 Warrants are exercisable at a price of \$0.53 per share, in whole or in part, at any time and from time to time from June 19, 2013 through December 19, 2017. The expiration date of the 2012 Warrants may be accelerated at the Issuer’s option if the shares of Common Stock meet certain price thresholds and the Common Stock underlying the 2012 Warrants is registered for resale pursuant to an effective registration statement or is freely transferable without volume limitations pursuant to Rule 144 under the Securities Act.

(d) N/A.

(e) N/A.

Item 6.

Contracts, Arrangements, Understanding or