

SIGMA TAU INTERNATIONAL SA
Form SC 13D/A
October 02, 2009

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

SCHEDULE 13D/A1 (Amendment No. 1)

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)

September 24, 2009

(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 .

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 | | 1,190,770 |
| Beneficially Owned | (8) | SHARED VOTING POWER |
| | | 47,951,620 |
| by Each | (9) | SOLE DISPOSITIVE POWER |
| Reporting | | 1,190,770 |
| Person With | (10) | SHARED DISPOSITIVE POWER |
| | | 47,951,620 |
- (11) AGGREGATE AMOUNT BENEFICIALLY OWNED BY EACH REPORTING PERSON
49,142,390
- (12) CHECK IF THE AGGREGATE AMOUNT IN ROW (11) EXCLUDES CERTAIN SHARES
- (13) PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (11)
26.3% (based on 167,424,666 shares of Common Stock outstanding as of August 10, 2009, 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 August 14, 2009, plus 17,352,569 shares of Common Stock issued by the Issuer pursuant to its private placement in September 2009, as reported in the Issuer's Current Report on Form 8-K, filed pursuant to the Securities Exchange Act of 1934, as amended, with the Securities and Exchange Commission on September 29, 2009, plus 1,976,284 shares of Common Stock issuable upon exercise of the Warrant (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)
Claudio 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
- (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 Owned | (8) | SHARED VOTING POWER |
| | | 47,595,520 |
| by Each | (9) | SOLE DISPOSITIVE POWER |
| Reporting | | 0 |
| Person With | (10) | SHARED DISPOSITIVE POWER |
| | | 47,595,520 |
- (11) AGGREGATE AMOUNT BENEFICIALLY OWNED BY EACH REPORTING PERSON
47,595,520
- (12) CHECK IF THE AGGREGATE AMOUNT IN ROW (11) EXCLUDES CERTAIN SHARES
- (13) PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (11)
25.5% (based on 167,424,666 shares of Common Stock outstanding as of August 10, 2009, 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 August 14, 2009, plus 17,352,569 shares of Common Stock issued by the Issuer pursuant to its private placement in September 2009, as reported in the Issuer's Current Report on Form 8-K, filed pursuant to the Securities Exchange Act of 1934, as amended, with the Securities and Exchange Commission on September 29, 2009, plus 1,976,284 shares of Common Stock issuable upon exercise of the Warrant (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 Owned | (8) | SHARED VOTING POWER |
| | | 47,595,520 |
| by Each | (9) | SOLE DISPOSITIVE POWER |
| Reporting | | 0 |
| Person With | (10) | SHARED DISPOSITIVE POWER |
| | | 47,595,520 |
- (11) AGGREGATE AMOUNT BENEFICIALLY OWNED BY EACH REPORTING PERSON
47,595,520
- (12) CHECK IF THE AGGREGATE AMOUNT IN ROW (11) EXCLUDES CERTAIN SHARES
- (13) PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (11)
25.5% (based on 167,424,666 shares of Common Stock outstanding as of August 10, 2009, 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 August 14, 2009, plus 17,352,569 shares of Common Stock issued by the Issuer pursuant to its private placement in September 2009, as reported in the Issuer's Current Report on Form 8-K, filed pursuant to the Securities Exchange Act of 1934, as amended, with the Securities and Exchange Commission on September 29, 2009, plus 1,976,284 shares of Common Stock issuable upon exercise of the 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 Owned | (8) | SHARED VOTING POWER |
| | | 47,595,520 |
| by Each | (9) | SOLE DISPOSITIVE POWER |
| Reporting | | 0 |
| Person With | (10) | SHARED DISPOSITIVE POWER |
| | | 47,595,520 |
- (11) AGGREGATE AMOUNT BENEFICIALLY OWNED BY EACH REPORTING PERSON
47,595,520
- (12) CHECK IF THE AGGREGATE AMOUNT IN ROW (11) EXCLUDES CERTAIN SHARES
- (13) PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (11)
25.5% (based on 167,424,666 shares of Common Stock outstanding as of August 10, 2009, 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 August 14, 2009, plus 17,352,569 shares of Common Stock issued by the Issuer pursuant to its private placement in September 2009, as reported in the Issuer's Current Report on Form 8-K, filed pursuant to the Securities Exchange Act of 1934, as amended, with the Securities and Exchange Commission on September 29, 2009, plus 1,976,284 shares of Common Stock issuable upon exercise of the 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 Owned | (8) | SHARED VOTING POWER |
| | | 47,595,520 |
| by Each | (9) | SOLE DISPOSITIVE POWER |
| Reporting | | 0 |
| Person With | (10) | SHARED DISPOSITIVE POWER |
| | | 47,595,520 |
- (11) AGGREGATE AMOUNT BENEFICIALLY OWNED BY EACH REPORTING PERSON
47,595,520
- (12) CHECK IF THE AGGREGATE AMOUNT IN ROW (11) EXCLUDES CERTAIN SHARES
- (13) PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (11)
25.5% (based on 167,424,666 shares of Common Stock outstanding as of August 10, 2009, 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 August 14, 2009, plus 17,352,569 shares of Common Stock issued by the Issuer pursuant to its private placement in September 2009, as reported in the Issuer's Current Report on Form 8-K, filed pursuant to the Securities Exchange Act of 1934, as amended, with the Securities and Exchange Commission on September 29, 2009, plus 1,976,284 shares of Common Stock issuable upon exercise of the 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 Owned | (8) | SHARED VOTING POWER |
| | | 47,595,520 |
| by Each | (9) | SOLE DISPOSITIVE POWER |
| Reporting | | 0 |
| Person With | (10) | SHARED DISPOSITIVE POWER |
| | | 47,595,520 |
- (11) AGGREGATE AMOUNT BENEFICIALLY OWNED BY EACH REPORTING PERSON
47,595,520
- (12) CHECK IF THE AGGREGATE AMOUNT IN ROW (11) EXCLUDES CERTAIN SHARES
- (13) PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (11)
25.5% (based on 167,424,666 shares of Common Stock outstanding as of August 10, 2009, 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 August 14, 2009, plus 17,352,569 shares of Common Stock issued by the Issuer pursuant to its private placement in September 2009, as reported in the Issuer's Current Report on Form 8-K, filed pursuant to the Securities Exchange Act of 1934, as amended, with the Securities and Exchange Commission on September 29, 2009, plus 1,976,284 shares of Common Stock issuable upon exercise of the 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. 1 by Paolo Cavazza, an Italian citizen, Claudio 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, Claudio 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 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.

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, Claudio Cavazza, Sigma-Tau Finanziaria, Sigma-Tau International, Sigma-Tau America and Sigma-Tau Pharmaceuticals. Claudio Cavazza directly and indirectly owns 57% of Sigma-Tau Finanziaria. 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 Claudio Cavazza and 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, Chaumiére-Consultadoria e Servicos SDC Unipessoal LDA (“Chaumiére”) purchased 356,100 shares of Common Stock in the open market at an average cash purchase price of \$0.267 per share. Chaumiére used its working capital to purchase such shares. Chaumiére is 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 “Warrant”), 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 may be accelerated at the Issuer’s option if the shares of Common Stock meets certain price thresholds and the Common Stock underlying the Warrant is registered for resale pursuant to an effective registration statement or are freely transferable without volume restrictions pursuant to Rule 144 under the Securities Act of 1933, as amended.

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. If it is determined that such nominee cannot be nominated for the 2009 annual election of the Issuer's Board of Directors, the Issuer shall appoint such nominee to fill any current vacancy that exists on the Issuer's Board of Directors.

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 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 49,142,390 shares of Common Stock representing 26.3% (based on 167,424,666 shares of Common Stock outstanding as of August 10, 2009, 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 August 14, 2009, plus 17,352,569 shares of Common Stock issued by the Issuer pursuant to its private placement in September 2009, as reported in the Issuer's Current Report on Form 8-K, filed pursuant to the Securities Exchange Act of 1934, as amended, with the Securities and Exchange Commission on September 29, 2009, plus 1,976,284 shares of Common Stock issuable upon exercise of the Warrant (as defined below)).

Claudio Cavazza is the beneficial owner of 47,595,520 shares of Common Stock representing 25.5% (based on 167,424,666 shares of Common Stock outstanding as of August 10, 2009, 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 August 14, 2009, plus 17,352,569 shares of Common Stock issued by the Issuer pursuant to its private placement in September 2009, as reported in the Issuer's Current Report on Form 8-K, filed pursuant to the Securities Exchange Act of 1934, as amended, with the Securities and Exchange Commission on September 29, 2009, plus 1,976,284 shares of Common Stock issuable upon exercise of the Warrant (as defined below)).

Sigma-Tau Finanziaria is the beneficial owner of 47,595,520 shares of Common Stock representing 25.5% (based on 167,424,666 shares of Common Stock outstanding as of August 10, 2009, 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 August 14, 2009, plus 17,352,569 shares of Common Stock issued by the Issuer pursuant to its private placement in September 2009, as reported in the Issuer's Current Report on Form 8-K, filed pursuant to the Securities Exchange Act of 1934,

as amended, with the Securities and Exchange Commission on September 29, 2009, plus 1,976,284 shares of Common Stock issuable upon exercise of the Warrant (as defined below)).

Sigma-Tau International is the beneficial owner of 47,595,520 shares of Common Stock representing 25.5% (based on 167,424,666 shares of Common Stock outstanding as of August 10, 2009, 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 August 14, 2009, plus 17,352,569 shares of Common Stock issued by the Issuer pursuant to its private placement in September 2009, as reported in the Issuer's Current Report on Form 8-K, filed pursuant to the Securities Exchange Act of 1934, as amended, with the Securities and Exchange Commission on September 29, 2009, plus 1,976,284 shares of Common Stock issuable upon exercise of the Warrant (as defined below)).

Sigma-Tau America is the beneficial owner of 47,595,520 shares of Common Stock representing 25.5% (based on 167,424,666 shares of Common Stock outstanding as of August 10, 2009, 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 August 14, 2009, plus 17,352,569 shares of Common Stock issued by the Issuer pursuant to its private placement in September 2009, as reported in the Issuer's Current Report on Form 8-K, filed pursuant to the Securities Exchange Act of 1934, as amended, with the Securities and Exchange Commission on September 29, 2009, plus 1,976,284 shares of Common Stock issuable upon exercise of the Warrant (as defined below)).

Sigma-Tau Pharmaceuticals is the beneficial owner of 47,595,520 shares of Common Stock representing 25.5% (based on 167,424,666 shares of Common Stock outstanding as of August 10, 2009, 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 August 14, 2009, plus 17,352,569 shares of Common Stock issued by the Issuer pursuant to its private placement in September 2009, as reported in the Issuer's Current Report on Form 8-K, filed pursuant to the Securities Exchange Act of 1934, as amended, with the Securities and Exchange Commission on September 29, 2009, plus 1,976,284 shares of Common Stock issuable upon exercise of the Warrant (as defined below)).

(b) The number of shares of Common Stock as to which Paolo Cavazza has the sole power to vote or direct the vote is 1,190,770. The number of shares of Common Stock as to which Paolo Cavazza shares the power to vote or direct the vote is 47,951,620. The number of shares of Common Stock as to which Paolo Cavazza has the sole power to dispose or direct the disposition is 1,190,770. The number of shares of Common Stock as to which Paolo Cavazza shares the power to dispose or direct the disposition is 47,951,620.

The number of shares of Common Stock as to which Claudio Cavazza has the sole power to vote or direct the vote is zero. The number of shares of Common Stock as to which Claudio Cavazza shares the power to vote or direct the vote is 47,595,520. The number of shares of Common Stock as to which Claudio Cavazza has the sole power to dispose or direct the disposition is zero. The number of shares of Common Stock as to which Claudio Cavazza shares the power to dispose or direct the disposition is 47,595,520.

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 47,595,520. 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 47,595,520.

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 47,595,520. 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 47,595,520.

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 47,595,520. 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 47,595,520.

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 47,595,520. 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 47,595,520.

(c) On September 24, 2009, pursuant to a Securities Purchase Agreement dated as of September 23, 2009, Sigma-Tau Pharmaceuticals agreed to purchase and, on September 28, 2009, Sigma-Tau Pharmaceuticals purchased 3,952,569 shares of Common Stock for a cash purchase price of \$0.253 per share in a private placement. In consideration of the purchase of such shares, the Issuer issued the Warrant to Sigma-Tau Pharmaceuticals to purchase 1,976,284 shares of Common Stock, 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 may be accelerated at the Issuer's option if the Common Stock meets certain price thresholds and the Common Stock underlying the Warrant is registered for resale pursuant to an effective registration statement or are freely transferable without volume restrictions pursuant to Rule 144 under the Securities Act of 1933, as amended.

(d) N/A.

(e) N/A.

Item 6. Contracts, Arrangements, Understanding or
 Relationships with Respect to Securities of the Issuer.

Item 6 of the Schedule 13D is hereby amended and restated in its entirety as follows:

Pursuant to the Letter of Intent, the Issuer and Sigma-Tau Pharmaceuticals entered into a Registration Rights Agreement pursuant to which the Issuer has granted Sigma-Tau Pharmaceuticals certain demand and piggyback registration rights covering the shares of Common Stock sold pursuant to the Letter of Intent. Pursuant to the February 2009 Purchase Agreement, the Issuer has granted to Sigma-Tau Pharmaceuticals certain demand and piggyback registration rights covering the shares of Common Stock sold pursuant to the February 2009 Purchase Agreement.

Pursuant to the September 2009 Purchase Agreement, the Issuer and Sigma-Tau Pharmaceuticals entered into a registration rights agreement pursuant to which the Issuer has agreed to file a reg-

istration statement covering the shares of Common Stock sold pursuant to the September 2009 Purchase Agreement and the shares of Common Stock issuable upon exercise of the Warrant.

The Issuer has agreed in the September 2009 Purchase Agreement that, until 60 days after the closing of the transaction under the September 2009 Purchase Agreement, neither it nor any of its subsidiaries will issue any shares of Common Stock or any security that entitles the holder thereof to receive Common Stock except pursuant to certain exempted issuances.

Except as otherwise set forth in Items 3 and 4 and this Item 6 of this Schedule 13D, to the best knowledge of the Reporting Parties there are no other contracts, arrangements, understandings or relationships (legal or otherwise) among the persons named in Item 2 and between such persons and any person with respect to any securities of the Issuer, including but not limited to, transfer or voting of any of the securities of the Issuer, finders fees, joint ventures, loan or oppositions arrangements, puts or calls, guarantees of profits, division of profits or loss, or the giving or withholding of proxies, or a pledge or contingency the occurrence of which would give another person voting power over the securities of the Issuer.

Item 7. Material to Be Filed as Exhibits.

Item 7 of the Schedule 13D is hereby amended and restated in its entirety as follows:

- A. Joint Filing Agreement dated October 2, 2009 by and among Paolo Cavazza, Claudio Cavazza, Sigma-Tau Finanziaria S.p.A., Sigma-Tau Pharmaceuticals, Inc., Sigma-Tau America S.A. and Sigma-Tau International S.A.
- B. Power of Attorney, dated January 9, 2007, granted by Messrs. Dominique Audia and Luca Checchinato, directors of Sigma-Tau International S.A., in favor of Messrs. Gregg Lapointe and Don DeLillo¹
- C. Power of Attorney, dated January 9, 2007, granted by Messrs. Dominique Audia and Luca Checchinato, directors of Sigma-Tau America S.A., in favor of Messrs. Gregg Lapointe and Don DeLillo²
- D. Power of Attorney, dated January 10, 2007, granted by Mr. Paolo Cavazza in favor of Messrs. Antonio Nicolai and Maurizio Terenzi³

1 Incorporated by reference to the Reporting Person's Schedule 13G filed with the SEC on January 12, 2007.

2 Incorporated by reference to the Reporting Person's Schedule 13G filed with the SEC on January 12, 2007.

3 Incorporated by reference to the Reporting Person's Schedule 13G filed with the SEC on January 12, 2007.

E. Power of Attorney, dated January 10, 2007, granted by Mr. Claudio Cavazza, President of Sigma-Tau Finanziaria S.p.A., in favour of Messrs. Antonio Nicolai and Maurizio Terenzi⁴

F. Power of Attorney, dated January 10, 2007, granted by Mr. Claudio Cavazza in favor of Messrs. Antonio Nicolai and Maurizio Terenzi⁵

G. Form of Letter of Intent dated November 26, 2008⁶

H. Form of Common Stock Purchase Agreement dated as of February 11, 2009⁷

I. Form of Securities Purchase Agreement⁸

J. Form of Warrant⁹

4 Incorporated by reference to the Reporting Person's Schedule 13G filed with the SEC on January 12, 2007.

5 Incorporated by reference to the Reporting Person's Schedule 13G filed with the SEC on January 12, 2007.

6 Incorporated by reference to Exhibit 10.1 to the Issuer's Current Report on Form 8-K filed with the SEC on December 1, 2008.

7 Incorporated by reference to Exhibit 10.44 to the Issuer's Registration Statement on Form S-1 (333-157322) filed with the SEC on February 13, 2009.

8 Incorporated by reference to Exhibit 10.1 to the Issuer's Current Report on Form 8-K filed with the SEC on September 29, 2009.

9 Incorporated by reference to Exhibit 10.2 to the Issuer's Current Report on Form 8-K filed with the SEC on September 29, 2009.

SIGNATURE

After reasonable inquiry and to the best of my knowledge and belief, I certify that the information set forth in this statement with respect to Paolo Cavazza is true, complete and correct.

Date: October 2, 2009

PAOLO CAVAZZA

By: /s/ Maurizio
Terenzi
Name: Maurizio
Terenzi
Title: Proxy-holder
authorized

After reasonable inquiry and to the best of my knowledge and belief, I certify that the information set forth in this statement with respect to Claudio Cavazza is true, complete and correct.

Date: October 2, 2009

CLAUDIO
CAVAZZA

By: /s/ Maurizio
Terenzi
Name: Maurizio
Terenzi
Title: Proxy-holder
authorized

After reasonable inquiry and to the best of my knowledge and belief, I certify that the information set forth in this statement with respect to Sigma-Tau Finanziaria S.p.A. is true, complete and correct.

Date: October 2, 2009

SIGMA-TAU
FINANZIARIA
S.P.A.

By: /s/ Maurizio
Terenzi

Name: Maurizio
Terenzi
Title: Proxy-holder
authorized

After reasonable inquiry and to the best of my knowledge and belief, I certify that the information set forth in this statement with respect to Sigma-Tau International S.A. is true, complete and correct.

Date: October 2, 2009

SIGMA-TAU
INTERNATIONAL
S.A.

By: /s/ Gregg
Lapointe
Name: Gregg Lapointe
Title: Attorney-in-fact

After reasonable inquiry and to the best of my knowledge and belief, I certify that the information set forth in this statement with respect to Sigma-Tau America S.A. is true, complete and correct.

Date: October 2, 2009

SIGMA-TAU
AMERICA S.A.

By: /s/ Gregg
Lapointe
Name: Gregg Lapointe
Title: Attorney-in-fact

After reasonable inquiry and to the best of my knowledge and belief, I certify that the information set forth in this statement with respect to Sigma-Tau Pharmaceuticals, Inc. is true, complete and correct.

Date: October 2, 2009

SIGMA-TAU
PHARMACEUTICALS,
INC.

By: /s/ Gregg
Lapointe
Name: Gregg Lapointe
Title: Chief Executive
Officer

The original statement shall be signed by each person on whose behalf the statement is filed or his authorized representative. If the statement is signed on behalf of a person by his authorized representative (other than an executive officer or general partner of the filing persons), evidence of the representative's authority to sign on behalf of such persons shall be filed with the statement; provided, however, that a power of attorney for this purpose which is already on file with the Commission may be incorporated by reference. The name and any title of each person who signs the statement shall be typed or printed beneath his signature.

Attention: Intentional misstatements or omissions of fact constitute Federal criminal violations (See 18 U.S.C. 1001)

Page 17 of 25

SCHEDULE A

Sigma Tau Finanziaria S.p.A.

The (a) name, (b) business address, (c) present principal occupation or employment and the name, principal business and address of any corporation or other organization in which such employment is conducted and (d) citizenship of each executive officer and director (other than Messrs. E. Cavazza, Jones, Platé, Artali and Cerrina Feroni) of Sigma-Tau Finanziaria are set forth below:

1. (a) Claudio Cavazza, (b) Via Pontina Km. 30,400, Pomezia (Rome), Italy, 00040, (c) President, and (d) Italy.
2. (a) Ugo Di Francesco, (b) Via Sudafrica, 20, Rome, Italy 00144, (c) Vice President and Chief Executive Officer, and (d) Italy.
3. (a) Marco Codella, (b) Via Sudafrica, 20, Rome, Italy 00144, (c) Managing Director, and (d) Italy.
4. (a) Mauro Bove, (b) Via Sudafrica, 20, Rome, Italy 00144, (c) Managing Director, and (d) Italy.
5. (a) Stefano Marino, (b) Via Pontina Km. 30,400, Pomezia (Rome), Italy, 00040, (c) General Counsel of Sigma-Tau Industrie Farmaceutiche Riunite SpA; Corporate Legal and Intellectual Property Director at Sigma-Tau Finanziaria SpA, and (d) Italy.

The (a) name, (b) business address, (c) present principal occupation or employment and the name, principal business and address of any corporation or other organization in which such employment is conducted and (d) citizenship of each director (other than Messrs. C. Cavazza, Di Francesco, Codella, Bove and Marino) of Sigma-Tau Finanziaria are set forth below:

1. (a) Enrico Cavazza, (b) Via Pontina Km. 30,400, Pomezia (Rome), Italy, (c) executive, Sigma-Tau Industrie Farmaceutica Riunite SpA, and (d) Italy.
2. (a) Trevor Jones, (b) Woodhyrst House, 18 Friths Drive, REIGATE, Surrey, Great Britain, (c) professor, and (d) Great Britain.
3. (a) Emilio Platé, (b) Via Finocchiaro Aprile n.5, Varese, Italy, (c) business consultant, and (d) Italy.
4. (a) Mario Artali, (b) Piazza F. Meda 4, Milano, Italy 20121, (c) Deputy Chairman, Banca Popolare di Milano, and (d) Italy.
5. (a) Marco Cerrina Feroni, (b) Piazza Paolo Ferrari 10, Milano, Italy 20121, (c) executive, Intesa Sanpaolo SpA, and (d) Italy.

The (a) name, (b) business address, (c) present principal occupation or employment and the name, principal business and address of any corporation or other organization in which such employment is conducted and (d) citizenship of each controlling person of Sigma-Tau Finanziaria are set forth below:

1. (a) Claudio Cavazza, (b) Pontina Km. 30,400, Pomezia (Rome), Italy 00040, (c) President, Sigma Tau, and (d) Italy.
2. (a) Paolo Cavazza, (b) Via Tesserete, 10, Lugano, Switzerland, (c) entrepreneur, Sigma Tau, Aptafin SpA and Esseti S.A., and (d) Italy.

Claudio Cavazza directly and indirectly owns 57% of Sigma Tau and Paolo Cavazza directly and indirectly owns 38% of Sigma Tau.

Sigma-Tau International S.A.

The (a) name, (b) business address, (c) present principal occupation or employment and the name, principal business and address of any corporation or other organization in which such employment is conducted and (d) citizenship of each executive officer and director of Sigma-Tau International are set forth below:

1. (a) Ugo Di Francesco, (b) Via Sudafrica, 20, Rome, Italy 00144, (c) Vice President and Chief Executive Officer of Sigma Tau Finanziaria S.P.A, located at Via Sudafrica 20 – 00144 Rome (Italy), and (d) Italy.
2. (a) Dominique Audia, (b) 19/21 Boulevard du Prince Henri - L-1724 Luxembourg, (c) Manager of Société Européenne de Banque S.A located at 19/21 Boulevard du Prince Henri - L-1724 Luxembourg, and (d) French.
3. (a) Mauro Bove, (b) Via Sudafrica, 20, Rome, Italy 00144, (c) Managing Director of Sigma Tau Finanziaria S.P.A, located at Via Sudafrica 20, and (d) Italy.
4. (a) Antonio Nicolai, (b) Via Pontina Km. 30,400, Pomezia (Rome), Italy, 00040, (c) President of Sigma Tau Pharmaceuticals located at 9841 Washingtonian Blvd, Suite 500- Gaithersburg MD 20878, and (d) Italy.
5. (a) Luca Checchinato, (b) 19/21 Boulevard du Prince Henri L-1724 Luxembourg, (c) Manager of Société Européenne de Banque S.A, located at 19/21 Boulevard du Prince Henri - L-1724 Luxembourg, and (d) Italy.
6. (a) Francesco Moglia, (b) 19/21 Boulevard du Prince Henri -L-1724 Luxembourg, (c) Manager of Société Européenne de Banque S.A. located at 19/21 Boulevard du Prince Henri - L-1724 Luxembourg, and (d) Italy.
7. (a) Gustave Stoffel, (b) 31, Boulevard Grande – Duchesse Charlotte- L – 1331 Luxembourg, (c) CEO of Profida Luxembourg located at 31, Boulevard Grande – Duchesse Charlotte- L – 1331 Luxembourg, and (d) Luxembourg.

Sigma-Tau America S.A.

The (a) name, (b) business address, (c) present principal occupation or employment and the name, principal business and address of any corporation or other organization in which such employment is conducted and (d) citizenship of each director of Sigma-Tau America are set forth below:

1. (a) Luca Checchinato, (b) 19/21 Boulevard du Prince Henri L-1724 Luxembourg, (c) Manager of Société Européenne de Banque S.A, located at 19/21 Boulevard du Prince Henri - L-1724 Luxembourg, and (d) Italy.
2. (a) Antonio Nicolai, (b) Via Pontina Km. 30,400, Pomezia (Rome), Italy, 00040, (c) President of Sigma Tau Pharmaceuticals located at 9841 Washingtonian Blvd, Suite 500- Gaithersburg MD 20878, and (d) Italy.

3. (a) Dominique Audia, (b) 19/21 Boulevard du Prince Henri - L-1724 Luxembourg, (c) Manager of Société Européenne de Banque S.A, located at 19/21 Boulevard du Prince Henri - L-1724 Luxembourg, and (d) French.
4. (a) Cristobalina Moron, (b) 19/21 Boulevard du Prince Henri - L-1724 Luxembourg, (c) Employee of Société Européenne de Banque S.A, located at 19/21 Boulevard du Prince Henri - L-1724 Luxembourg, and (d) French.
5. (a) Mauro Bove, (b) Via Sudafrica, 20, Rome, Italy 00144, (c) Managing Director of Sigma Tau Finanziaria S.P.A, located at Via Sudafrica 20, and (d) Italy.
6. (a) Christophe Velle, (b) 19/21 Boulevard du Prince Henri - L-1724 Luxembourg, (c) Manager of Société Européenne de Banque S.A located at 19/21 Boulevard du Prince Henri - L-1724 Luxembourg, and (d) French.

Sigma-Tau Pharmaceuticals. Inc.

The (a) name, (b) business address, (c) present principal occupation or employment and the name, principal business and address of any corporation or other organization in which such employment is conducted and (d) citizenship of each director of Sigma-Tau Pharmaceuticals are set forth below:

1. (a) Antonio Nicolai, (b) Via Pontina Km. 30,400, Pomezia (Rome), Italy, 00040, (c) President, and (d) Italy.
2. (a) Gregg Lapointe, (b) 9841 Washingtonian Blvd, Suite 500- Gaithersburg MD 20878, (c) Chief Executive Officer, and (d) United States.
3. (a) Ugo Di Francesco, (b) Via Sudafrica, 20, Rome, Italy 00144, (c) Vice President and Chief Executive Officer of Sigma-Tau Finanziaria S.p.A. located at Via Sudafrica 20, Rome, Italy 00144, and (d) Italy.
4. (a) Mauro Bove, (b) Via Sudafrica, 20, Rome, Italy 00144, (c) Head Corporate & Business Development of Sigma-Tau Finanziaria S.p.A. located at Via Sudafrica 20, Rome, Italy 00144, and (d) Italy.
5. (a) Stefano Marino, (b) Via Pontina Km. 30,400, Pomezia (Rome), Italy, 00040, (c) General Counsel of Sigma-Tau Industrie Farmaceutiche Riunite SpA located at Via Pontina Km. 30,400, Pomezia (Rome), Italy; Corporate Legal and Intellectual Property Director at Sigma-Tau Finanziaria SpA located at Via Sudafrica 20, Rome, Italy 00144, and (d) Italy.
6. (a) Paolo Carminati, (b) Via Pontina Km. 30,400, Pomezia (Rome), Italy, 00040, (c) Corporate Research & Development Director of Sigma-Tau Industrie Farmaceutica Riunite SpA, located at Via Pontina Km. 30,400, Pomezia (Rome), Italy, and (d) Italy.
7. (a) Marco Codella, (b) Via Sudafrica, 20, Rome, Italy 00144, (c) Managing Director of Sigma-Tau Finanziaria S.p.A., and (d) Italy.

EXHIBIT INDEX

	Page
A. Joint Filing Agreement dated October 2, 2009 by and among Paolo Cavazza, Claudio Cavazza, Sigma-Tau Finanziaria S.p.A., Sigma-Tau Pharmaceuticals, Inc., Sigma-Tau America S.A. and Sigma-Tau International S.A.	24
B. Power of Attorney, dated January 9, 2007, granted by Messrs. Dominique Audia and Luca Checchinato, directors of Sigma-Tau International S.A., in favor of Messrs. Gregg Lapointe and Don DeLillo ¹	
C. Power of Attorney, dated January 9, 2007, granted by Messrs. Dominique Audia and Luca Checchinato, directors of Sigma-Tau America S.A., in favor of Messrs. Gregg Lapointe and Don DeLillo ²	
D. Power of Attorney, dated January 10, 2007, granted by Mr. Paolo Cavazza in favor of Messrs. Antonio Nicolai and Maurizio Terenzi ³	
E. Power of Attorney, dated January 10, 2007, granted by Mr. Claudio Cavazza, President of Sigma-Tau Finanziaria S.p.A., in favour of Messrs. Antonio Nicolai and Maurizio Terenzi ⁴	
F. Power of Attorney, dated January 10, 2007, granted by Mr. Claudio Cavazza in favor of Messrs. Antonio Nicolai and Maurizio Terenzi ⁵	

-
- 1 Incorporated by reference to the Reporting Person's Schedule 13G filed with the SEC on January 12, 2007.
 - 2 Incorporated by reference to the Reporting Person's Schedule 13G filed with the SEC on January 12, 2007.
 - 3 Incorporated by reference to the Reporting Person's Schedule 13G filed with the SEC on January 12, 2007.
 - 4 Incorporated by reference to the Reporting Person's Schedule 13G filed with the SEC on January 12, 2007.
 - 5 Incorporated by reference to the Reporting Person's Schedule 13G filed with the SEC on January 12, 2007.

G. Form of Letter of Intent dated November 26, 2008⁶

H. Form of Common Stock Purchase Agreement dated as of February 11, 2009⁷

I. Form of Securities Purchase Agreement⁸

J. Form of Warrant⁹

6 Incorporated by reference to Exhibit 10.1 to the Issuer's Current Report on Form 8-K filed with the SEC on December 1, 2008.

7 Incorporated by reference to Exhibit 10.44 to the Issuer's Registration Statement on Form S-1 (333-157322) filed with the SEC on February 13, 2009.

8 Incorporated by reference to Exhibit 10.1 to the Issuer's Current Report on Form 8-K filed with the SEC on September 29, 2009.

9 Incorporated by reference to Exhibit 10.2 to the Issuer's Current Report on Form 8-K filed with the SEC on September 29, 2009.

EXHIBIT A

JOINT FILING AGREEMENT

The undersigned hereby agree that the amended and restated statement on Schedule 13D with respect to the Common Stock of Soligenix, Inc. dated as of October 2, 2009 is, and any amendments thereto signed by each of the undersigned shall be, filed on behalf of each of us pursuant to and in accordance with the provisions of Rule 13d-1(f) under the Securities Exchange Act of 1934.

Dated: October 2, 2009

PAOLO CAVAZZA

By: /s/ Maurizio Terenzi
Name: Maurizio Terenzi
Title: Proxy-holder authorized

Dated: October 2, 2009

CLAUDIO CAVAZZA

By: /s/ Maurizio Terenzi
Name: Maurizio Terenzi
Title: Proxy-holder authorized

Dated: October 2, 2009

SIGMA-TAU FINANZIARIA S.P.A.

By: /s/ Maurizio Terenzi
Name: Maurizio Terenzi
Title: Proxy-holder authorized

Dated: October 2, 2009

SIGMA-TAU INTERNATIONAL S.A.

By: /s/ Gregg Lapointe
Name: Gregg Lapointe
Title: Attorney-in-fact

Dated: October 2, 2009

SIGMA-TAU AMERICA S.A.

By: /s/ Gregg Lapointe
Name: Gregg Lapointe
Title: Attorney-in-fact

Dated: October 2, 2009

SIGMA-TAU PHARMACEUTICALS, INC.

By: /s/ Gregg Lapointe
Name: Gregg Lapointe
Title: Attorney-in-fact

Page 25 of 25