Current Agreements

Dealdoc

Second amendment to development and supply agreement for BA058 microneedle patch

3M
3M Drug Delivery Systems
Radius Health

Sep 16 2010

Second amendment to development and supply agreement for BA058 microneedle patch

Companies:	3M 3M Drug Delivery Systems Radius Health
Announcement date:	Sep 16 2010
Amendment date:	Sep 16 2010
Related contracts:	Development agreement for transdermal delivery of BA058 First amendment to development and supply agreement for BA058 microneedle patch Development and supply agreement for BA058 microneedle patch Evaluation agreement for BA058 microneedle patch Third amendment to development and supply agreement for BA058 microneedle patch Fourth amendment to development and supply agreement for BA058 microneedle patch Fifth amendment to development and supply agreement for BA058 microneedle patch

Details

Announcement date:	Sep 16 2010
Amendment date:	Sep 16 2010
Start date:	Sep 16 2010
Industry sectors:	Pharmaceutical Drug delivery
Asset type:	Compound Technology
Therapy areas:	Musculoskeletal » Osteoporosis
Technology types:	Drug delivery » Transdermal Small molecules
Deal components:	Development Supply
Stages of development:	Formulation

Financials

Termsheet

Not available.

Press Release

Not available.

Filing Data

Not available.

Contract

Second Amendment To Development and Clinical Supplies Agreement*

This Amendment, dated September 16, 2010 by and between 3M Company, and 3M Innovative Properties Company having a principal office at 3M Center, Building 275-3E-10, St. Paul, MN 55144-1000 (hereinafter “3M”), and Radius Health Inc. having a principal office at 300 Technology Square, Cambridge, MA (hereinafter “Radius”) amends the Development and Clinical Supplies Agreement dated June 19, 2009 (hereinafter “the Agreement”) as follows:

RECITALS:

A. Whereas, 3M and Radius have previously entered into a Development and Clinical Supplies Agreement dated June 19, 2009 (“Agreement”) for the development and delivery of clinical supplies up through Phase II for a BA058 coated MTS product (“Product”);

B. Whereas, Radius has conducted preclinical and clinical trials with Product; including a Phase Ia clinical trial with Product which rendered results that did not meet predetermined criteria;

C. Whereas, Radius is willing to repeat the Phase Ia clinical trial with new Product made by 3M using a different, proprietary array material;

D. Whereas, 3M is willing to manufacture new clinical supplies of Product at its own expense subject to the terms of this Amendment.

E. Whereas, Radius also requires additional clinical supplies, including Phase Ib supplies.

F. Whereas, 3M will have the capability or producing Phase II supplies by [*] and will assume the capital expenditures costs for Phase II supplies;

G. Whereas, all terms of the Agreement not explicitly amended by this Amendment shall remain in full force and effect. To the extent not modified or defined by this Amendment, all capitalized and defined terms shall have the meaning ascribed to them in the Agreement.

NOW, THEREFORE, in consideration of the Recitals (which are incorporated herein) and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. 3M shall manufacture three (3) doses plus Placebo of Phase Ia/b clinical supplies of Product using 3M’s proprietary array material in quantities and for such uses as set forth below. Phase Ia will be provided at 3M’s expense. Included in the runs shall be small quantities of [*] mcg and Placebo ([*] each) for preclinical studies. Such supplies shall be manufactured in [*] with a target release of approximately [*] ([*]) weeks after each run. The supplies will be manufactured in the following order: [*] mcg, Placebo, [*] mcg and [*] mcg. Production of the [*] mcg dose is targeted for the week of [*], with the target release date on or before [*]. The Placebo is targeted to be released within a week or less afterwards. The [*] mcg and [*] mcg doses are targeted

---

* Confidential Treatment Requested by the Registrant. Redacted Portion Filed Separately with the Commission.

1

---

to be released one and two weeks after that, respectively. The preclinical supplies, [*] mcg and Placebo, are targeted to be released under quarantine by [*] and [*], respectively.

[*] mcg dose

[*] mcg dose

[*] mcg dose

Placebo

Study supplies (Phase 1+7-day tox)

[*]

[*]

[*]

[*]

Extras

[*]

[*]

[*]

[*]

Retains

[*]

[*]

[*]

[*]

Release

[*]

[*]

[*]

[*]

Stability

[*]

[*]

[*]

[*]

[*]

[*]

[*]

[*]

Needed Arrays

[*]

[*]

[*]

[*]

Total with [*]% overage

[*]

[*]

[*]

[*]

2. 3M shall conduct a limited stability protocol on all three doses of the clinical supplies of Product. The stability protocol shall include two storage conditions: 4C/ambient humidity with [*] ([*]) pull[*] ([*] month[*]), not including release, and 25C/60%RH with a [*] ([*]) pull[*] at [*] month[*]. 3M shall also conduct a limited stability protocol on the ready-to-coat (RTC) solutions for Phase 1a/b supplies. The stability protocol shall include one storage condition: 4C/ambient humidity with [*] ([*]) pull[*] ([*] month[*]) for each solution. The RTC solution will also be tested prior to each manufacturing run for confirmation of formulation. 3M shall invoice Radius [*] Dollars ($[*]) per pull point for this stability testing at the conclusion of testing of the each pull.

3. Upon request by 3M, Radius shall provide 3M with certain requested preclinical and clinical data generated by Radius under any previous Workplans; Radius shall not be required to provide preclinical or clinical data to 3M in the event and to the extent that the relevant data is being used or intended for use to support a patent application unless the parties mutually agree upon a method of disclosure that does not present a risk to the integrity of the applicable patent application. 3M shall have the right to use the preclinical and clinical data provided by Radius pursuant to this Section 3 (as well as any preclinical and clinical data previously provided to 3M by Radius) for purposes of marketing its MTS technology, so long as 3M does not disclose (i) the identity of Radius, (ii) the identity of BA058, or (iii) any information related to BA058 that would allow any third party to ascertain the identity of BA058, the therapeutic areas for which BA058 is useful for, including but not limited to the prevention and/or treatment of osteoporosis. Before disclosing any Radius preclinical or clinical data provided pursuant to this Section 3 (as well as any preclinical and clinical data previously provided to 3M by Radius), 3M shall provide Radius with a draft of the portions of any proposed disclosure that contain such data no fewer than [*] ([*]) days prior to the

---

* Confidential Treatment Requested by the Registrant. Redacted Portion Filed Separately with the Commission.

---

planned disclosure date so that Radius may review the planned disclosure and confirm that it does not disclose any of the information covered by (i)-(iii). 3M shall comply with Radius' reasonable request to delete references to information covered by (i)-(iii). If there is a dispute regarding publications, such dispute shall be resolved by the parties and will include an undertaking by each party to propose scientifically meaningful equivalent disclosure that does not disclose the information covered by (i)-(iii). It is specifically understood that disclosure of preclinical and/or clinical information to 3M under this Section 3 shall not alter its status (if applicable) as Radius Confidential Information. It is further understood that after a disclosure has been approved by Radius under this Section 3 and approved that disclosure may be reused in the same format without resort to a separate review by Radius. Radius also agrees to provide 3M with certain requested clinical data generated under any future Workplans upon Radius approval, which shall not be unreasonably withheld, and subject to the limitations set forth above with respect to data generated by Radius under previous Workplans.

4. 3M shall provide approximately [*] ([*]) Phase Ib supplies (included in the table above in (1)) 3M shall invoice Radius for such supplies on a time and material basis. The estimated cost for the Phase Ib supplies is $[*].

5. 3M shall provide proof to Radius that a DMF reference letter is on file. 3M shall provide Radius with an updated CMC section and finalized non-redacted copies of preclinical and clinical reports describing safety of the TAZ arrays, as well as any other information necessary for Radius regulatory filings.

6. 3M shall provide up to [*] ([*]) applicators for clinical use.

7. The term of the Agreement shall be extended until June 19, 2013.

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be duly executed in duplicate as of the date and year the last Party signs below.

ACCEPTED AND AGREED TO:

3M COMPANY

Radius Health, Inc.

By

/s/ Jim A. Vaughan

By

/s/ B.N. Harvey

Print Name

Jim A. Vaughan

Print Name

B.N. Harvey

Title

Division VP & GM

Title

CFO and SVP

Date

Sept. 22, 2010

Date

16 Sept, 2010

3M INNOVATIVE PROPERTIES COMPANY

By

/s/ Robert W. Sprague

---

* Confidential Treatment Requested by the Registrant. Redacted Portion Filed Separately with the Commission.

3

Print Name

Robert W. Sprague

Title

Secretary

Date

9-20-2010

ACR # 201004140

4