

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

The General Hospital Corporation,)	
)	
Plaintiff)	
v.)	Civil Action No.:
)	
Seelos Therapeutics, Inc.,)	
)	
Defendant.)	
)	

COMPLAINT

Plaintiff, The General Hospital Corporation d/b/a Massachusetts General Hospital (hereinafter, “Plaintiff” or “MGH”), by and through its undersigned attorneys, hereby complains against Defendant, Seelos Therapeutics, Inc. (hereinafter, “Defendant” or “Seelos”), and states as follows:

PARTIES

1. MGH is a Massachusetts not-for-profit corporation with its principal place of business at 55 Fruit Street, Boston, Massachusetts 02114.
2. Upon information and belief, Seelos is a Nevada corporation with its principal place of business at 300 Park Avenue, New York, New York.

VENUE & JURISDICTION

3. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a) because Plaintiff and Defendant are citizens of different states and the amount in controversy exceeds \$75,000.
4. This Court has personal jurisdiction over Defendant because this cause of action arose based on events, breaches, and omissions related to the Clinical Research Support Agreement executed by Plaintiff and Defendant on December 14, 2020 (hereinafter, the

“Agreement”). Section 15.4 of the Agreement provides that “[e]ach party agrees to submit to the exclusive jurisdiction of the United States District Court for the District of Massachusetts with respect to any claim, suit, or action in law or equity arising in any way out of this Agreement or the subject matter thereof.”

5. Venue is proper in this district pursuant to 28 USC § 1391(b) because a substantial part of the events or omissions giving rise to the claim occurred in this district.

FACTUAL BACKGROUND

I. The Sean M. Healey and AMG Center for ALS

6. MGH is a not-for profit corporation that created the Sean M. Healey and AMG Center for ALS (hereinafter, “Healey Center”).

7. The Healey Center is a non-profit research center on a quest to discover life-saving therapies for the approximately 500,000 people worldwide affected by amyotrophic lateral sclerosis (hereinafter, “ALS”).

8. The Healey Center relies on its longstanding partnerships with people and institutions within the ALS community – from patients and caregivers to physicians and advocacy organizations – to further and fund this mission. It receives philanthropic donations that fund its staff and its groundbreaking work in researching and treating ALS.

9. It was as a direct result of those partnerships and philanthropic donations that the Healey Center was able to launch the groundbreaking HEALEY ALS Platform Trial in 2018, which is the first ever platform trial for ALS.

II. Seelos Therapeutics, Inc.

10. Seelos is a for-profit corporation focused on the development of pharmaceutical products for commercial sale.

11. Seelos is a publicly traded corporation that began trading on the Nasdaq stock exchange on January 24, 2019.

12. On or about February 19, 2019, Seelos completed the acquisition of a drug candidate known as trehalose (also known as SLS-005) from Bioblast Pharma, Ltd. At the time, trehalose was being studied for use in treatment of Sanfilipo syndrome.

13. Seelos consistently announced in press releases its desire to expand the indications for trehalose beyond Sanfilipo syndrome.

14. To that end, on August 25, 2020, Seelos received authorization from the FDA to proceed with a Phase IIb/III trial of trehalose for the treatment of ALS.

15. Shortly thereafter Seelos and MGH executed the Clinical Research Support Agreement that would govern that clinical trial (hereinafter, the “Study”) and would ultimately form the basis of the dispute in this matter.

III. The Agreement

16. The Agreement was executed on December 14, 2020 by and between Mr. Raj Mehra, PhD as CEO of Seelos, and Kristin Collins as Agreement Associate for MGH.

17. In executing the Agreement, Seelos agreed that trehalose would be clinically tested as part of the revolutionary HEALEY ALS Platform Trial.

18. Pursuant to that Agreement, MGH would lend its physicians’ extensive experience and knowledge in clinical ALS research to complete the Study, which Seelos needed to seek FDA approval of trehalose for use in treatment of ALS.

19. The Agreement specifically obligated MGH to “provide clinical trial design, management and regulatory services in support of this clinical investigation,” including both clinical trial design as well as trial management and operations. Agreement at Ex. A.

20. MGH also was required to “provide comprehensive biostatistical design, analysis, and reporting services through MGH staff biostatisticians and an external consulting firm.” *Id.*

21. In exchange for access to the platform trial, to extensive clinical trial design and management services, and to MGH’s physicians’ specialized expertise, Seelos agreed to make fixed payments to MGH to support the Study. *Id.*

22. Pursuant to Section 4.2 of the Agreement, MGH was to issue invoices to Seelos and Seelos was obligated to either make full payment of the amount owed or to present MGH with a dispute as to the amount owed within thirty (30) days of receipt of such an invoice.

23. In Exhibit A to the Agreement, the parties initially agreed to an estimated \$635,884 for clinical trial design, an additional \$11,175,119 for the Double Blind period, and up to \$5,200,000 for the Open-Label Extension period. *Id.* at Exhibit A; *see also id.* at Exhibit C. However, as was made explicitly clear in the Agreement, the initial budget was for oral administration of trehalose, and IV administration of the drug during the trial would increase the estimated cost. *Id.* at Exhibit A.

24. As anticipated, on September 23, 2021, Amendment 1 to the Agreement was executed by both parties and replaced the original Exhibit C Fee Schedule with a new, Exhibit D Fee Schedule. Exhibit 2 (Amendment 1) at 1. At that time, Seelos agreed “to support the Study with a research grant of approximately” \$17,920,500 for both the Clinical Trial Design (\$635,884) and Double Blind (\$17,284,616) Periods. *Id.* at Exhibit D.

25. The parties then executed Amendments 2 and 3 to the Agreement, which both related to the Open-Label Extension Period.

26. Amendment 2 became effective as of May 27, 2022, and provided a detailed budget for the anticipated \$788,392 cost for the first three months of the Open-Label Extension Study. Exhibit 3 (Amendment 2) at Exhibit D-1.

27. Amendment 3 to the Agreement became effective as of July 12, 2022 and amended the Fee Schedule to include additional periods for the Open-Label Extension Study, with a total budgeted cost of \$8,323,583 (including the previously negotiated \$788,392). Exhibit 4 (Amendment 3) at Exhibit D-2.

28. The parties then executed the final Amendment, Amendment 4, that was effective as of May 24, 2023. Michael Goleblew, Chief Financial Officer of Seelos executed the Amendment on May 23, 2023 on behalf of Seelos. That amendment updated the fixed fees chart and increased the Double Blind budget slightly from \$17,284,616 to \$17,617,808, while maintaining the same \$635,884 budget for Clinical Trial Design. The amendment further decreased the Open Label Extension Study budget from \$8,323,583 to \$4,776,465.

29. Pursuant to Amendment 4, the last patient last visit (LPLV) date for the the LPLV date for the Open Label Extension Phase 1 Period was set to be May 31, 2023, and the LPLV date for the Double Blind Period was set to be August 31, 2023. Both study periods were to end on December 31, 2023, and a final invoice was to be sent on March 1, 2024.

IV. Seelos Failed to Pay for Its Clinical Trial

30. Despite Seelos's CFO's execution of the latest amendment at the end of May 2023, and again pledging its financial support for these costs, Seelos immediately began to fall behind on its contractual payments.

31. As contemplated by Exhibit D-3 to Amendment 4, MGH issued two invoices for \$1,200,000 each to Seelos on June 27, 2023,¹ a third invoice for \$1,800,000 to Seelos on August 1, 2023, and a fourth invoice for \$1,800,000 to Seelos on November 1, 2023.

32. With the exception of one partial payment of \$500,000 on October 17, 2023, Seelos neither paid these invoices, nor disputed any of the charges thereon within the thirty (30) days as required by Section 4.2 of the Agreement. *See* Ex. 1 at § 4.2.

33. Seelos raised its first objection to any invoice on December 14, 2023. That was one hundred and five (105) days after the LPLV date of August 31, 2023, forty-four (44) days after the November 1, 2023 invoice was issued, and nine (9) days after MGH's legal counsel sent the first demand for payment of the past due amounts.

34. Not only was the objection untimely per Section 4.2 of the Agreement, it was also directly contradicted by documents previously executed by Seelos's representatives.

35. Specifically, Seelos stated that MGH improperly included patients receiving RELYVRIO® in the Study population and sought to reduce the amount owed to MGH by \$2,000,000 as a result.

36. However, as later pointed out by MGH's legal counsel, both Study protocols executed by Seelos's representatives on April 13, 2023 and October 10, 2023 explicitly contemplate the existence of patients receiving RELYVRIO® at baseline and starting RELYVRIO® post-baseline.

¹ These invoices were for fixed payments due in February and May 2023. The invoices were not issued until after execution of Amendment #4, as the parties continued to negotiate the budgeted (and therefore the fixed fee) amounts.

37. Seelos never explained how it could dispute inclusion of RELYVRIO® patients when they were explicitly included in the Study protocols executed by its own representatives, nor did it ever explain how it calculated the claimed \$2,000,000 discount.

38. Seelos made one additional partial payment in the amount of \$2,000,000 on February 2, 2024.

39. Pursuant to the Agreement, MGH issued the final invoice to Seelos for \$1,202,058 on March 1, 2024.

40. Through undersigned counsel, MGH has again made a demand for payment of the \$4,702,058.00 due and owing pursuant to the duly issued August 1, 2023, November 1, 2023, and March 1, 2024 invoices.

41. Seelos has failed to make any payments towards that arrearage since its last payment on February 2, 2024.

COUNT I – BREACH OF CONTRACT

42. Paragraphs 1 through 41 are incorporated as if fully set forth herein.

43. Seelos executed the Agreement and subsequent four amendments, whereby it agreed to pay MGH the amount due pursuant to the terms of the Agreement and amendments in the amount due pursuant to the periodic invoices provided by MGH.

44. MGH's first June 27, 2023 invoice required payment of \$1,200,000.00.

45. MGH's second June 27, 2023 invoice required payment of \$1,200,000.00.

46. MGH's August 1, 2023 invoice required payment of \$1,800,000.00.

47. MGH's November 1, 2023 invoice required payment of \$1,800,000.00.

48. MGH's March 1, 2024 invoice required payment of \$1,202,058.00.

49. Seelos has made partial payments totaling \$2,500,000.00 towards these invoices.

50. More than 30 days have passed since the issuance of these invoices.

51. In accordance with the parties' Agreement and amendments, Seelos is now justly indebted to MGH.

52. MGH has made proper demand for payment on Seelos, but full payment has not been made to MGH.

53. Seelos is currently indebted to MGH in the amount of \$4,702,058.00.

**COUNT II – BREACH OF IMPLIED COVENANT OF
GOOD FAITH AND FAIR DEALING**

54. Plaintiff repeats and realleges the allegations contained in Paragraphs 1 through 53 above and incorporates them herein by reference.

55. The Agreement is a valid contract in Massachusetts that includes an implied covenant of good faith and fair dealing.

56. Defendant breached the implied covenant of good faith and fair dealing, including by failing to make payments due under the Agreement and by making false and untimely allegations regarding the inclusion of RELIVRIO® patients in the Study as a means of justifying its nonpayment.

57. Defendant further breached the implied covenant of good faith and fair dealing by, *inter alia*, misrepresenting that it had sufficient funds to meet its contractual obligations and, instead, upon information and belief, relying upon speculative future investments.

58. As a result of Defendant's breach, Plaintiff was harmed in multiple ways including damages in an amount to be proven at trial.

COUNT III - FRAUD

59. Paragraphs 1 through 58 are incorporated as if fully set forth herein.

60. Seelos made false statements to MGH regarding its ability to fund the clinical trial contemplated by the Agreement. These false representations included, but are not limited to, executing Amendment 4 on May 23, 2023, which provided that Seelos agreed to support the study with a research grant of \$23,030,157, including a total of \$7,202,058 still due and owing beginning immediately after execution of Amendment 4.

61. Seelos and/or its representatives knew that the above representation was false when made or made these representations with a reckless indifference to the truth of them.

62. Seelos's representatives made the above representations with the intent to conceal Seelos's intent not to pay MGH for work performed, and to induce MGH to continue to work and incur costs.

63. MGH justifiably relied on the above representations and continued to provide services to Seelos.

64. Seelos has failed to fully pay for those services.

65. As a result of MGH's justifiable reliance on the above representations, MGH was damaged.

COUNT IV – UNJUST ENRICHMENT

66. Paragraphs 1 through 65 are incorporated as if fully set forth herein.

67. Seelos has been unjustly enriched and benefited from MGH's services worth \$4,702,058.00 without compensating MGH.

68. MGH has demanded that Seelos satisfy this deficiency by paying the balance owed, but Seelos has failed to do so and there remains a balance due in the amount of \$4,702,058.00.

COUNT V - UNFAIR AND DECEPTIVE TRADE PRACTICES
(MASS. GEN. LAWS CH. 93A § 1 ET SEQ. & § 11)

69. Paragraphs 1 through 68 are incorporated as if fully set forth herein.

70. Seelos is a biopharmaceutical company engaged in trade or commerce.

71. Seelos has engaged in unfair methods of competition or committed an unfair or deceptive act or practice in trade and commerce, and such acts were willful and knowing under the meaning of Mass. Gen. L. c. 93A §§ 2 and 11, and a loss of money or property has been suffered by MGH as a result of Defendants' acts.

72. Seelos' unfair methods of competition and unfair or deceptive acts or practices include and are not limited to compelling Plaintiff to continue the Study at Plaintiff's expense under the empty promise of payment, which, upon information and belief, Defendant knew it had no ability to pay and had no intention of ultimately paying. These actions constitute violations of M.G.L. c. 93A.

73. Defendant's unfair methods of competition and unfair or deceptive acts occurred primarily and substantially within Massachusetts, including because Defendant compelled Plaintiff to continue conducting the Study in Massachusetts.

74. Due to Defendant's violations of M.G.L. c. 93A as set forth above, Plaintiff is entitled to three times the amount of damages found, as well as attorneys' fees, and costs.

WHEREFORE, Plaintiff respectfully requests that this Honorable Court:

A. Enter judgment for Plaintiff against Defendant in an amount of to be determined at trial, including prejudgment and post-judgment interest, costs, and attorneys' fees, as well as treble damages pursuant to M.G.L. c. 93A; and

B. Grant Plaintiff such other and further relief as justice requires.

Respectfully submitted,

The General Hospital Corporation

By Its Attorneys,

WELTS, WHITE & FONTAINE, P.C.

Date: November 11, 2024

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